

**GUIDELINES FOR PRESCRIBING  
PSYCHOTROPIC DRUGS**

**MINISTRY OF HEALTH**

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## **Foreword**

These "Guidelines for Prescribing Psychotropic Drugs" are promulgated by the Ministry of Health to assist in the promotion of good practice in the prescription of psychotropic drugs in New Zealand.

These guidelines are addressed primarily to psychiatrists, but we hope they will be useful to general practitioners, psychiatric nurses, consumers and all those who are involved in the prescription, administration or use of psychotropic drugs.

The bulk of the guidelines consist of those guidelines issued in 1995 by the Royal Australian and New Zealand College of Psychiatrists. The Ministry of Health acknowledges the assistance provided by this College in permitting the use of their guidelines in this document.

The introductory section, written largely by Professor Trevor Silverstone, addresses the principles and context of prescription of psychotropic drugs. I would like to thank all of the members of the working group for their efforts in producing these guidelines.

**Janice Wilson**  
**Director of Mental Health**

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## Disclaimer

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## **Introduction**

### **Justification**

Some 7-8% of the New Zealand population are likely to suffer from a major psychiatric disorder such as schizophrenia, mania or depressive illness at some point during their lives. Treatment for these disorders can be effective. Drug treatment is an important part of treatment of most of these disorders. Other, non-drug treatments are also important, but are not discussed in these guidelines. For such treatment to be maximally effective it needs to be prescribed at the appropriate dose for the optimal length of time. These guidelines are presented to assist prescribing doctors in achieving those objectives, and to provide suitable information about psychotropic drugs for consumers and caregivers, and for other health professionals.

### **Objectives**

These guidelines, based on those drawn up by the Quality Assurance Committee of the Royal Australian and New Zealand College of Psychiatrists, have been adopted by the Ministry of Health of New Zealand to promote good practice in the prescribing of psychotropic drugs in this country. Although the RANZCP guidelines were primarily addressed to psychiatrists, the principles on which they are based, and the detailed recommendations they contain apply to all who prescribe psychotropic drugs.

Psychotropic drugs are chemical substances which affect psychological functioning, both normal and abnormal. Those used in medical practice are targeted at ameliorating abnormal psychological symptoms. They do so by acting on neurotransmitter systems in the brain. There are a variety of medical uses for psychotropic drugs. These guidelines focus on the use of drugs in the treatment of mental disorders.

### **General Principles**

With the introduction of new brain imaging techniques we have gained a much greater understanding of the ways in which psychotropic drugs act. This has led to the development of compounds which have been designed to act at selected neurotransmitter receptors at specific anatomical sites. Despite this intent, most psychotropic drugs, particularly those developed in earlier years, are not site-specific, and affect several brain regions. This may explain why they have a large number of effects, some of which are undesirable side-effects.

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Many of the newer compounds have significant advantages over the earlier psychotropic drugs in terms of increased tolerability and greater safety. Unfortunately they are generally no more effective, nor do they act more quickly.

However selective the drug, and however well-tolerated, for optimal benefit it needs to be used appropriately.

1 Its use should be restricted to those conditions for which clinical efficacy has been determined by controlled clinical trials.

2 Dosage should be kept within the range recommended in these guidelines for the indication for which it is prescribed - lower doses are generally ineffective, higher doses can lead to unwanted side-effects or toxic reactions. In the elderly dose requirements are usually less.

3 For any drug treatment to work it needs to be taken consistently as recommended. If it is not taken consistently no decision can be made about whether it is effective or not.

4 Before prescribing more than one drug it is necessary to consider whether the proposed combination of treatments is therapeutically rational and safe. In a given clinical situation a combination of more than one psychotropic drug may well be appropriate, but this is by no means always the case (see below).

5 Of understandable concern to all involved is the possibility of unpleasant side effects, or adverse events. A full description of the likely side effects and frank discussion of the risk of adverse events occurring usually helps to allay this concern. People receiving treatment have an absolute right to know the relevant information about the drugs they are prescribed.

6 The optimal duration of treatment needs to be considered carefully at its onset and discussed fully. Some drugs (eg benzodiazepines) are best given for a strictly limited period; others may need to be taken long-term (eg lithium for bipolar disorder).

In the first, introductory section of the guidelines, these six points are considered in more detail.

The subsequent sections deal with individual drugs arranged by therapeutic class, rather than by diagnostic groups. For each drug the following information is given: its indications; the recommended dose range; the usual duration of treatment required; potentially dangerous interactions. The information is presented in the form of a quality assurance proforma. This allows ready assessment of individual prescriptions in the light of currently recommended practice.

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## Appropriate indications

While some psychotropic drugs (eg chlorpromazine) have a wide range of acceptable indications, that of some others is much more restricted (eg clozapine should be reserved for patients suffering from schizophrenia who do not respond to standard antipsychotics ['treatment-resistant']). The names of certain of the therapeutic classes of drugs do not always convey the breadth of indications in which they may be effective. For example many of the drugs classified as antidepressants, particularly the selective serotonin reuptake inhibitors (SSRI), have been shown to of significant benefit in conditions other than depression, such as obsessive compulsive disorder (OCD) and bulimia nervosa.

When choosing a drug for a particular indication the risk/benefit ratio should be taken into account. For example in the treatment of anxiety the benefits of benzodiazepine compounds (section 3 of the guidelines) in relieving the symptoms of anxiety (which may be incapacitating) must be weighed against the danger of producing physical dependence. Antipsychotic drugs (section 5) may cause extrapyramidal side effects, including tardive dyskinesia. They are therefore not recommended for treatment of anxiety.

## Dose

The aim is to find the minimum effective dose. This is frequently achieved by trial and error, although in certain cases it is essential to monitor blood levels of psychotropic drugs. Prescribing a psychotropic drug at a dose smaller than the lowest recommended in the guidelines is likely to prove ineffective, while a dose which is greater than the maximum recommended may present unnecessary risk.

Whenever it is thought clinically necessary to exceed the maximum recommended dose, the reasons for doing so should be fully documented, and the treatment programme discussed with a colleague, as well as with the person receiving treatment. Higher doses of antipsychotic drugs have been prescribed in the management of a disturbed psychotic state. However, there is good evidence to show that higher doses of antipsychotic drugs (eg haloperidol greater than 20mg per day) are rarely more effective than standard doses, and at the same time markedly increase the risk of serious adverse effects. In this situation short-term use of an adjunctive medication (such as a benzodiazepine), rather than increasing the dose of antipsychotic, is a better therapeutic strategy. Whenever the dose exceeds that recommended in the guidelines regular review needs to be undertaken.

Some indications require higher doses of a particular drug than others. For example, in the treatment of bulimia nervosa the effective dose of a selective serotonin reuptake inhibitor (SSRI) is likely to be higher than that generally given for the treatment of a depressive disorder. But even in such cases, the recommended range should not be exceeded without complying with the advice given in section 1.3 of the guidelines.

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The elderly may only tolerate doses of psychotropic drugs lower than those required by younger people. There are two reasons for this:

- 1 Liver and/or kidney function is more likely to be impaired, leading to less efficient metabolism and excretion (pharmacokinetics). This causes the blood level of the drug to rise, which in turn increases the risk of adverse effects. Impaired metabolism and excretion can also prolong the action of a drug. For example, in the elderly the effects of a hypnotic drug taken before retiring may last well into the next day ('hangover effect'), thereby leading to an increased risk of accidents.
- 2 The aging brain is more sensitive to the effects of psychotropic drugs (pharmacodynamics). This is the likely explanation for the nocturnal confusion often seen in the elderly following even a low dose of a hypnotic drug.

Thus for the elderly the starting dose should be at the lower end of the recommended dose range, or even below it.

Some psychotropic drugs, in particular the tricyclic antidepressants, are potentially fatal when taken in overdose. Therefore when prescribing for a depressed person it is essential to enquire about possible suicidal ideation, and to limit the amount of drug to be dispensed on any one prescription.

### **'When required' (PRN) drug treatment**

People in hospital may be prescribed extra doses in addition to those given at predetermined intervals. This is charted to be given as required by the clinical state, usually at the discretion of the nursing staff. It is most important that the doctor prescribing such 'prn' treatment clearly documents the following:

- 1 The circumstances in which such treatment should be given
- 2 The generic name of the drug to be administered
- 3 The dose to be given
- 4 The route by which it is to be administered
- 5 How often it may be given
- 6 The maximum amount of each drug which can be given in any 24 hour period

It is advisable to review such prn prescriptions regularly.

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On each occasion prn treatment is administered nursing staff should document why it was thought to be required. It is recommended that prn treatment should be reviewed should it become necessary to administer 50% of the maximum daily dose in any 12 hour period.

## **Prevention of relapse**

This assumes particular importance in the long-term treatment of schizophrenia and recurrent affective disorder. fifty percent of people who have schizophrenia or bipolar disorder (manic-depressive illness) do not take their medication as prescribed. That is the commonest cause of relapse in these two conditions.

The costs of relapse are high to the individuals concerned, to their families, and to the health care system. In addition, the medicine which is not taken may accumulate in the home. This creates a potential source of danger to young children, as well as providing a ready means of self-harm for those contemplating suicide.

The prescribing doctor is frequently unaware that treatment is not being taken. It is good practice to ask about this when repeating a prescription for long-term drug-treatment.

Adherence to a treatment programme can be improved in a number of ways.

1 Communication Ongoing education and discussion about the natural history of the illness and the place of drug treatment in the prevention of relapse allows people to make a more informed judgement about their treatment. The education process should involve all members of the the treatment team.

2 Drug regime This should be kept as simple as possible. A single daily dose of one psychotropic drug is more likely to be taken as directed than multiple dosing involving more than one drug. If the drug regime is at all complex detailed instructions need to be given, preferably in writing. Surveys have shown that many, especially the elderly, have little idea of either the frequency or the number of tablets they should be taking. Individual blister packaging is often helpful.

Adherence to antipsychotic drugs can be further improved by regular administration of the drug in the form of a depot injection administered every 1-4 weeks by a psychiatric nurse. This approach has a number of advantages, which include: a) regular support by a health team member in the community; b) early warning of any deterioration in clinical state, thereby allowing appropriate intervention at the earliest opportunity.

3 Side-effects Doctors should respond promptly and sympathetically to reports of possible side-effects, always taking them seriously. In many cases appropriate dose reduction will suffice. Many psychotropic drugs can cause sexual difficulties which people may be reluctant to volunteer, and because of which

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they stop taking their drug treatment. Doctors should enquire about these during consultations for repeat prescriptions. Another frequently overlooked side effect, which women in particular find unacceptable, is weight gain. This occurs in some 20-30% of patients treated with phenothiazine antipsychotics (section 5), lithium (section 7) or tricyclic antidepressants (section 8). Changing to an alternative drug of the same therapeutic class may often lead to a gratifying reduction in the excess weight, (eg substituting carbamazepine for lithium, an SSRI for a tricyclic antidepressant).

4 Support Regular support by a member of the mental health team working in the community can do a great deal to reduce the risk of relapse. It should be considered for all those receiving long-term treatment, and their support network.

## **Drug combinations**

A combination of more than one psychotropic drug may be required for a number of reasons. These include: enhancing the therapeutic action of the primary drug; treating dual pathology; countering the side-effects of the primary drug. Other combinations of psychotropic drugs are less well-founded. For example, it is not usually a good idea to combine two drugs of the same therapeutic class; this practice (polypharmacy) is irrational in pharmacological terms, and is unlikely to add any therapeutic benefit and likely to increase the risk of adverse reactions. Finally the possibility of untoward drug interactions should always be borne in mind when combining psychotropic drugs. These can arise because one drug affects the metabolism of the other (pharmacokinetic interaction), or because their pharmacological effects are additive (pharmacodynamic interaction).

1 Enhancing therapeutic action A proportion of people suffering from severe depression fail to respond to treatment with an antidepressant drug prescribed in an adequate dose for a sufficient length of time ['resistant depression']. Adding lithium improves the clinical state in up to a third of those with resistant depression.

2 Treating dual pathology People with 'psychotic depression' who show the characteristic features of a severe depressive illness plus delusional ideas, frequently fail to respond adequately to antidepressant drug treatment alone. The addition of an antipsychotic drug often leads to greater overall improvement.

3 Countering side-effects In the initial stages of treatment antipsychotic drugs cause extrapyramidal symptoms (pseudoparkinsonism or akathisia) in 25-33% of people. These symptoms are often alleviated by adding an anticholinergic antiparkinsonian compound such as procyclidine or benztropine; for akathisia a beta-adrenergic blocking compound such as propranolol may be helpful. Such combination therapy is rarely required for long, and the need for it should be reviewed at monthly intervals.

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4 Polypharmacy The pharmacologically unjustified practice of prescribing two drugs of the same therapeutic class is all too frequently seen in the treatment of schizophrenia. This affords little if any therapeutic advantage. Furthermore it is not a good idea to prescribe one antipsychotic compound as a depot and another to be taken orally; it is much easier to evaluate the contribution that a compound is making to therapeutic response and side-effects when given alone, than when two similar drugs given in combination. If regular depot medication is failing to ameliorate the clinical condition sufficiently, the dose and frequency of depot injections should be adjusted to obtain optimum results. If it becomes necessary temporarily to add an oral antipsychotic, this should be the same drug as is being given by depot injection.

5 Drug interactions Before combining two psychotropic drugs, or adding a psychotropic drug to the treatment regime of a person already receiving drugs for another condition, it is always as well to consider the possibility of an untoward drug interaction. This is particularly relevant in the elderly. Common important potential interactions are given in the guidelines for each class of drug under the heading 'concomitancy'. These lists are by no means exhaustive - when in doubt ask a pharmacist or drug information centre for advice or consult a pharmacopoeia.

### **Adverse events**

In addition to their primary therapeutic properties psychotropic drugs generally have a number of other pharmacological actions, many of which can cause unwanted symptoms (side-effects). It is essential that people are warned about the more likely side-effects whenever they are prescribed a drug for the first time (eg the risk of dystonic reaction in young adults). This tends to allay anxiety about the symptom in question should it occur, because it can then be attributed to the drug rather than worrying that it might herald a worsening of their condition or that it is the development of another illness.

Side effects should be asked about at each consultation. Some, such as extrapyramidal symptoms, are readily apparent on examination. Where possible, appropriate remedial action should be taken, either by adjusting the dose of the drug suspected to be responsible, or by adding another drug to counter the unwanted effects of the first. Those receiving antipsychotic drugs long-term should be examined for the presence of tardive dyskinesia (TD) every three months.

The developing foetus is at particular risk from certain psychotropic drugs given to the mother during gestation. Lithium, for example, when given during the first trimester of pregnancy, is known to increase the likelihood of a congenital heart abnormality. The relative risks and benefits of continuing a drug known to carry a risk to the foetus, in a woman contemplating pregnancy, need to be discussed fully with her, and preferably her partner, as soon as pregnancy is contemplated. Some drugs are contraindicated in nursing mothers because they are concentrated in breast milk and can thereby adversely

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affect the infant. Again it is important to discuss this with the mother well before delivery so that she can decide about subsequent breast feeding in the context of her required psychotropic medication.

## **Duration of treatment**

The likely duration of treatment should be discussed when starting. It is all too frequently the case that treatment once started continues for much longer than is necessary or desirable. If the individual is told that it is not in his or her best interest to continue on a particular medication for more than a stated length of time, he or she will be much less likely to seek repeat prescriptions. On the other hand, there are treatments which once started should continue long-term. If it is known from the outset how long the treatment is likely to last, it is more likely that the treatment will be taken.

1 Time-limited treatment Of particular importance in this respect is treatment with benzodiazepine drugs for anxiety and insomnia. For anxiety such treatment should not continue for more than eight weeks at most (section 3). Not only does efficacy wear off but physical dependence can occur. This makes discontinuation very uncomfortable and even dangerous, due to withdrawal symptoms. While most prescribers are aware of this possibility when prescribing a benzodiazepine drug for the treatment of anxiety, they seem to be less aware of it when prescribing a benzodiazepine or other hypnotic for insomnia, and fail to limit the duration of treatment. Since most hypnotics lose their efficacy after one or two weeks (due to tolerance) there is little point in prescribing them for longer, and the guidelines caution against this (section 4). Furthermore, trying to stop after continuous use is generally followed by a worsening of the insomnia (due to physical dependence). A recent random population survey in New Zealand revealed that over 3% of women take a benzodiazepine drug on a regular basis. Rational prescribing as recommended in the guidelines would greatly improve this situation.

2 Continuous treatment There are certain psychiatric conditions where psychotropic drugs should be taken continuously for extended periods. This is particularly true for schizophrenia and bipolar disorder. Many controlled clinical trials attest to the continued efficacy of antipsychotic drugs in preventing relapse in schizophrenia and of mood stabilisers in preventing relapse in bipolar disorder. Where, despite medical advice to the contrary, a person clearly states that he or she wishes to stop taking the drug treatment every effort should be made to support them during the withdrawal period.

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## Consumer information

Before any course of drug treatment is started, full information should be given about the benefits to be expected, and possible side effects. For compulsorily detained patients this right is enshrined in Section 67 of the Mental Health (Compulsory Assessment and Treatment) Act 1992: *"Every patient is entitled to receive an explanation of the expected effects of any treatment offered to the patient, including expected benefits and the likely side effects, before the treatment is commenced"*

When the individual's mental states prevents full understanding of these issues before treatment takes effect, every effort should be made to provide the relevant information about benefits and side effects to their support network. Following improvement, full discussion about benefits and side effects should take place with the individual at the earliest opportunity.

Other aspects of psychotropic drug treatment which should be discussed fully at the outset, or soon after, are: 1) the expected duration of treatment; 2) who is going to supervise the treatment; 3) how often the individual will be asked to attend for review of treatment; 4) where treatment will be given (particularly relevant to those prescribed treatment with a depot antipsychotic preparation); 5) recommended restriction of alcohol intake while on treatment; 6) appropriate dietary advice.

At subsequent consultations other issues should be discussed, such as potential long-term effects (if the treatment is to be continued for longer than six months), and in the case of a woman of child-bearing age, the implications the treatment may have for pregnancy and breast feeding.

The more a person knows about his or her treatment the more effective the therapeutic alliance is likely to be. This in turn will lead to the optimum benefit - the therapeutic goal to be aimed for whenever a drug is prescribed.

## Fostering a Therapeutic Alliance

People being considered for, or receiving drug treatment are more likely to cooperate with the treatment, or to be honest if they do not take the treatment as prescribed, if:

- they are treated with respect
- their fears and experiences are taken seriously and responded to
- they are fully informed on their condition, options for treatment and the desired and unwanted effects of treatment
- they are part of an active support network of their own choosing

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## Recommended Reading

The following references are recommended for further reading:

Drug Treatment in Psychiatry (5th edition) by Trevor Silverstone and Paul Turner, Routledge, London, 1995

Treatments of Psychiatric Disorders, American Psychiatric Association, Washington, 1989

The Use of Drugs in Psychiatry (4th edition) by John Cookson, John Crammer and Bernard Heine, Gaskell, London, 1993

Handbook of Affective Disorders (2nd edition) edited by Eugene S Paykel, Churchill Livingstone, Edinburgh, 1992

The Psychopharmacology and Treatment of Schizophrenia edited by P B Bradley and S H Hirsch, Oxford Medical Publications, Oxford, 1986

Psychotropic Drug Guidelines (2nd edition), Victorian Drug Usage Advisory Committee, Victorian Medical Postgraduate Foundation Therapeutic Committee, Toorak, 1993

Manual of Clinical Psychopharmacology (2nd edition) by A Schatzberg and J O Cole, American Psychiatric Press Inc, Washington D C, 1991

An alternative view of psychotropic drug use is presented in:

Toxic Psychiatry by Peter Breggin, St Martin's Press, New York, 1991

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## **RANZCP Prescribing Guidelines**

The following pages are reproduced from the guidelines drawn up by the Quality Assurance Committee of the Royal Australian and New Zealand College of Psychiatrists

### **1. Introduction**

#### **1.1 The role of these guidelines**

This publication aims to provide guidelines for psychiatrists to monitor their use and documentation of psychotropic medications in the management of patients with mental disorders. It is adapted for the Australian and New Zealand situation from the 1992 American Psychiatric Association "Manual of Psychiatric Quality Assurance" (with their permission). These guidelines can also be used for quality assurance programmes in various psychiatric settings, i.e. public hospitals (inpatient or outpatient), community or private practice, particularly in some form of peer review.

The guidelines are grouped under classes of psychotropic drugs, not diagnostic groups. This format is used as these are guidelines for monitoring the appropriate use of drugs, not prescriptions for the management of specific diagnostic categories. It is recognised that many other factors apart from those mentioned in these lists are taken into account in prescribing medication. Most importantly, medication will form only part of the management process.

It is important for psychiatrists to read the medical product information before prescribing medication, and to be vigilant in maintaining awareness of updates in product information that are issued from time to time by the manufacturer or distributor of the psychotropic drug.

The appropriate management of specific psychiatric disorders is well-addressed in "Psychotropic Drug Guidelines" (2nd edition, 1993), published by the Victorian Drug Usage Advisory Committee.

#### **1.2 Assumptions concerning the role of the psychiatrist in prescribing psychotropic medications**

It is presumed that these guidelines are applied in clinical situations where a psychiatrist, either individually or as part of a team, has assessed the patient by history taking and mental state examination. The prescribing psychiatrist should ensure that a physical examination has been performed by either himself/herself, a member of the treating team, or by the referring doctor. It is further assumed that these matters are recorded in the patient's notes, and that the psychiatrist (or another medical member of the team) has prescribed the medication in question. Further, it is assumed that any change of either the type or dosage of drug is documented in the patient's notes.

#### **1.3 Prescribing outside suggested criteria**

These guidelines do not aim to either proscribe certain practices, or prescribe what should be a correct use of psychotropic medication. Rather, they provide a checklist for each drug group, to be used as monitoring guidelines for prescribers, and also a trigger for review. While some of the items in the checklists, e.g. diagnostic indications and dosage ranges, imply standards which should usually be met, it is not suggested that practitioners can never deviate from these criteria. It is recognised that in any practice there will be a number of patients who are

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prescribed drugs outside the guidelines suggested, without this being poor clinical practice. This will vary with the nature of the treatment setting, the type of patients treated, and the patient's previous response to psychotropic agents. The following are examples of prescribing outside the criteria: medication used for diagnoses other than those suggested; dosage levels above, or below, those suggested; combinations of medications other than those suggested; prescription of medication in the presence of relative contra-indications; continued prescription of medication in the presence of adverse side-effects; and continued prescription of medication beyond the suggested duration.

The following principles should be followed when prescribing outside the criteria described in these guidelines:

1. The usual history-taking, examination and documentation process leading to the diagnosis should be followed.
2. There should be documentation of the decision-making that has led to the use of medication outside the guidelines, which may involve discussion with another colleague.
3. If appropriate, there should be referral for a second opinion.
4. There should be documentation that: i) information (including written material if possible) regarding the prescribing of the medication outside the suggested criteria has been passed on to patients and/or guardians (when appropriate), and ii) that appropriate informed consent has been obtained. Usually verbal consent would suffice. The decision making process should be mutual between patient and psychiatrist.

#### **1.4 Adverse drug reactions**

As a general principle, any significant adverse drug reactions (including deaths) should be reported to the appropriate regulatory authority, even if the relationship between the event and the drug may be unclear. In Australia this is the Adverse Drug Reactions Advisory Committee (ADRAC) of the Australian Drug Evaluation Committee (ADEC).

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## 2. Outline of Formats for Psychotropic Drug Prescription used in these Guidelines

The following formats (for inpatient and outpatient use respectively) indicate the basic structure of the guidelines for each specific drug class in this document. The notation "review if absent (or) present" (to the left of the criteria) indicates that there should be further consideration of the documentation and/or management if there is, respectively, the absence or presence of the criteria designated. For example, there should be further review if common professionally accepted indications for a particular psychotropic drug are absent. These review notations can, of course, be readily used in quality assurance assessment.

### A. Psychopharmacological criteria - inpatient documentation

*Review if:*

- |         |    |   |
|---------|----|---|
| absent  | A. | Common professional accepted indications  |
| absent  | B. | Minimal documentation (it is assumed that the treatment chart is part of the patient's clinical file)   |
|         |    | 1 History of psychiatric disorder   |
|         |    | 2 History of past allergic response or other adverse reactions to psychotropic drugs  |
|         |    | 3 Physical examination  |
|         |    | 4 Mental status examination   |
|         |    | 5 Diagnosis made by psychiatrist  |
|         |    | 6 Treatment plan developed or approved by psychiatrist  |
|         |    | 7 Medication order signed by psychiatrist or his/her delegate   |
|         |    | 8 Progress notes made and signed by psychiatrist or his/her delegate at appropriate intervals for level of activity   |
|         |    | 9 Nurses notes, daily recordings  |
|         |    | a Drug administration as ordered by psychiatrist  |
|         |    | b General clinical observations   |
|         |    | 10 Graphical recording including:   |
|         |    | a Vital signs e.g. temperature, pulse, respiration, blood pressure, as appropriate at intervals based on clinical judgement depending on medication doses and the individual patient. For example, for low potency antipsychotics such as chlorpromazine, once daily during the first two weeks of treatment, and for three days after dosage escalation, and subsequently at intervals based on clinical judgement |
|         |    | 11 Laboratory reports as ordered by psychiatrist or physician (basic laboratory tests include electrolytes, creatinine, full blood count and liver tests. Other required tests relevant to specific drugs are indicated in the following text. Specific investigations may be necessary for different disorders)  |
|         |    | 12 Discharge summary  |
| absent  | C. | Generally accepted dosage range   |
| present | D. | Unusual duration of therapy   |

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present	E.	Unusual concomitant prescribing
		1 Psychotropic medication
		2 Other medications
present	F.	Critical adverse developments
absent	G.	Critical adjunctive services (e.g. relevant laboratory investigations)
present	H.	Relative contra-indications
absent	I.	Other appropriate alternative treatments

**B. Psychopharmacological criteria - outpatient documentation**

*Review if:*

absent	A.	Common professional accepted indications
absent	B.	Minimal documentation
		1 History of psychiatric disorder
		2 History of past allergic response or other adverse reactions to psychotropic drugs
		3 Physical examination at the time of initial interview or by referring physician
		4 Mental state examination
		5 Diagnosis made by psychiatrist
		6 Treatment plan developed or approved by psychiatrist
		7 Record of medication prescribed by psychiatrist
Progress or treatment by psychiatrist		8 Progress notes by primary therapist on each patient visit. note by psychiatrist at least once every three months, whenever any major change in clinical status or
		9 Record of administration of any injection ordered by
		10 Laboratory reports
		11 Termination note if patient has left clinic at the time the review occurs
absent	C.	Generally accepted dosage range
present	D.	Unusual duration of therapy
present	E.	Unusual concomitant prescribing
		1 Psychotropic medication
		2 Other medications
present	F.	Critical adverse developments
absent	G.	Critical adjunctive services (e.g. relevant laboratory investigations)
present	H.	Relative contra-indications

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absent      i.      Other appropriate alternative treatments

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### 3. Anti-Anxiety Medications

#### A. Benzodiazepines

The prescribing of anti-anxiety medication in the form of benzodiazepines requires special care and precautions because of the risk of dependency. The importance of making an accurate diagnosis in all cases where benzodiazepines are used should be emphasised, and other forms of appropriate therapy should be considered.

It is recognised that any particular practitioner or unit may well have a number of patients who are taking benzodiazepines outside the suggested listed criteria. Reasons for this may include: alternative means of treatment have been ineffective; factors related to the patient's particular clinical state; patient preference; or efforts to reduce or cease the medication have caused significant distress to the patient. In these situations the actions listed under "Prescribing Outside Suggested Criteria" (outlined above) should apply, in addition to on-going supervision and review of both the patient's clinical state, and the type and dosage of medication.

The RANZCP Guidelines for the Use of Benzodiazepines, the NH & MRC "Guidelines for the Prevention and Management of Benzodiazepine Dependence" (National Health & Medical Research Council, monograph series no. 3, 1991, reprinted 1992), the "Psychotropic Drug Guidelines" (Victorian Drug Usage Advisory Committee, 2nd Edition, 1993), and the American Psychiatric Association Task Force Report on Benzodiazepine Dependence, Toxicity and Abuse (1990), are useful relevant documents.

#### Inpatient and outpatient criteria

*Review if:*

absent	A.	<u>Common indications (in psychiatric practice):</u>
		1 Anxiety disorders
		2 Anxiety associated with other medical and psychiatric disorders
		3 Alcohol or sedative withdrawal
		4 Akathisia
		5 Acute psychomotor agitation
		6 Acute situational anxiety
		7 As an adjunct to neuroleptics for sedative purposes in acute psychosis
florid		
absent	B.	Minimal documentation (see pages 4-6 above)
absent	C.	<u>Dosage Range:</u>
need		(note that dosage should be less in the elderly. Also note that doses to be titrated for those undergoing drug withdrawal)

Generic name	Dosage
Alprazolam	0.25-5 mg/day
Chlordiazepoxide	10-50 mg/day
Clonazepam	0.5-6 mg/day
Clorazepate	5-30 mg/day
Diazepam	2-25 mg/day
Lorazepam	1-6 mg/day
Oxazepam	7.5-90 mg/day

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present	D.	<u>Duration:</u>
	1	More than two changes of psychotropic medication type in any seven day period
	2	Period over two months
present	E.	<u>Concomitancy:</u>
	1	Any other benzodiazepine (except during transition from one to another)
	2	More than one other psychotropic medication of any class
	3	Any psychostimulant
present	F.	<u>Critical adverse development:</u>
	1	Marked sedation or lethargy after the first week
	2	Ataxia (especially in the elderly)
	3	Delirium or confusion (especially in the elderly)
	4	Intentional overdose
	5	Disinhibition or aggression
	6	Anterograde amnesia
	7	Falls or accidents (especially in the elderly)
	8	Severe withdrawal symptoms upon discontinuation (e.g. seizures)
absent	G.	<u>Critical adjunctive services</u>
	1	Thyroid function tests may be relevant
present	H.	<u>Relative contra-indications</u>
	1	History of hypersensitivity to this drug
	2	History of alcohol or drug abuse or dependence, other than for acute detoxification
	3	Pregnancy or breast feeding
	4	Children and adolescents
	5	Myasthenia gravis
	6	Sleep apnoea
	7	Severe respiratory disease
absent	I.	<u>Other treatment modalities attempted:</u>
		One or more of the following:
	1	Counselling
	2	Relaxation therapy
	3	Desensitisation
	4	Cognitive therapy
	5	Other medication
	6	Family therapy
	7	Individual psychotherapy
	8	Hypnotherapy
	9	Other relevant treatment

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## B. Buspirone

This medication is an azaspirodecanedione, a chemical and pharmacological class unrelated to the benzodiazepines. Buspirone is not cross-tolerant with the benzodiazepines. Unlike the benzodiazepines it has a gradual onset of anxiolytic action which may not occur for up to two weeks. The abuse and physical dependence potential of buspirone is low.

### Inpatient and outpatient criteria

Review if:

absent	A.	<u>Common indications (in psychiatric practice):</u> <ol style="list-style-type: none"><li>1 Anxiety disorders</li><li>2 Anxiety associated with other medical and psychiatric disorders</li></ol>
absent	B.	Minimal documentation (see pages 4-6 above)
absent	C.	<u>Dosage Range:</u> 10-60 mg/day
present	D.	<u>Duration:</u> <ol style="list-style-type: none"><li>1 More than two changes of psychotropic medication type in any seven day period</li><li>2 Period over two months</li></ol>
present	E.	<u>Concomitancy:</u> <ol style="list-style-type: none"><li>1 More than one other psychotropic medication of any class</li><li>2 Any psychostimulant</li></ol>
present	F.	<u>Critical adverse development:</u> <ol style="list-style-type: none"><li>1 Dizziness</li><li>2 Headache</li><li>3 Nervousness</li><li>4 Light-headedness</li><li>5 Intentional overdose</li><li>6 Falls or accidents (especially in the elderly)</li></ol>
absent	G.	<u>Critical adjunctive services</u> <ol style="list-style-type: none"><li>1 Thyroid function tests may be relevant</li></ol>
present	H.	<u>Relative contra-indications</u> <ol style="list-style-type: none"><li>1 History of hypersensitivity to this drug</li><li>2 Pregnancy or breast feeding</li><li>3 Children and adolescents</li><li>4 Sleep apnoea</li><li>5 Severe respiratory disease</li></ol>

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absent      I.      Other treatment modalities attempted

One or more of the following:

- 1      Counselling
- 2      Relaxation therapy
- 3      Desensitisation
- 4      Cognitive therapy
- 5      Other medication
- 6      Family therapy
- 7      Other relevant treatment

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## 4. Hypnotic Medications

The use of hypnotic medications requires particular care and precaution because of the risk of dependency. Determining the primary diagnosis (psychiatric or physical illness) is essential in the assessment of patients with sleep disorders. Non-pharmacological means of managing patients with insomnia should be considered.

It is recognised that there are some patients who will remain on hypnotics long-term because of their clinical state, failure of other treatments, and/or the extreme distress that the cessation of hypnotics can cause in some patients. The action taken as described under the heading "Prescribing Outside Suggested Criteria" (above) should be followed in such cases.

The RANZCP Guidelines for the Use of Benzodiazepines, the NH & MRC "Guidelines for the Prevention and Management of Benzodiazepine Dependence" (National Health & Medical Research Council, monograph series no. 3, 1991, reprinted 1992), the "Psychotropic Drug Guidelines" (Victorian Drug Usage Advisory Committee, 2nd Edition, 1993), and the American Psychiatric Association Task Force Report on Benzodiazepine Dependence, Toxicity and Abuse (1990), are useful relevant documents.

### Inpatient and outpatient criteria

*Review if:*

absent      A.      Common indications:

- 1      Insomnia
- 2      Night terrors

absent      B.      Minimal documentation

absent      C.      Dosage range:  
(note that dosage should be less in the elderly)

<b>Generic name</b>	<b>Dosage</b>
Flunitrazepam	1-2 mg
Flurazepam	15-30 mg
Nitrazepam	5-10 mg
Temazepam	10-20 mg
Triazolam	0.125 mg-0.25 mg
Chloral hydrate*	500-1000 mg

\* not a benzodiazepine; toxic in excess dosage

present      D.      Duration:

- 1      More than 14 days use

present      E.      Concomitancy:

- 1      More than one other psychotropic medication

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present	F.	<u>Critical adverse developments:</u>
		1 Prolonged daytime lethargy
		2 Ataxia (especially in the elderly)
		3 Delirium (especially in the elderly)
		4 Paradoxical excitement
		5 Respiratory depression
		6 Amnestic syndrome
		7 Intentional overdose
		8 Falls and accidents
		9 Gastric irritation (with chloral hydrate)
		10 Severe withdrawal symptoms after discontinuation
		11 Hallucinations
absent	G.	<u>Critical adjunctive services:</u>
		1 Basic laboratory studies on admission
present	H.	<u>Relative contra-indications:</u>
		1 History of addiction to sedative/hypnotic drugs or alcohol
		2 Pregnancy (especially first trimester) or breast feeding
		3 Known allergy to this group of drugs
		4 Age less than 15 years
		5 Hepatic or renal impairment (with chloral hydrate)
		6 Myasthenia gravis
		7 Sleep apnoea
		8 Severe respiratory disease
absent	I.	<u>Other management programmes for insomnia:</u>
and		1 Consideration and management of other psychiatric physical causes of secondary insomnia
		2 Specific non-pharmacological therapy
		3 Sleep hygiene methods

---

## 5. Antipsychotic Medications

### A. Classical antipsychotics

The indications for antipsychotic medications include a number of psychotic illnesses that have varied aetiologies. The various forms of schizophrenia, schizoaffective disorder, and organic brain syndromes with psychotic features are seen as the conditions for which these medications are most clearly indicated. However, the antipsychotics have also been shown to be effective in the treatment of bipolar disorder or of major depression with psychotic features (usually together with an antidepressant). In the primary affective disorders, unlike schizophrenia, the antipsychotics are more often indicated for the acute phase of treatment but are sometimes required for maintenance treatment as well.

The maximum dose listed in the Approved Production Information for most antipsychotic drugs may be less than that necessary for adequate treatment of some psychotic patients.

In view of the serious disability that can result from tardive dyskinesia, the increasing frequency with which the disorder is recognised, and its potential reversibility with early detection, specific comments should be included in the progress notes at least every 3 months, for patients on antipsychotic medication. The appropriate observation of tongue, face and general musculature is relatively brief and straight forward, and the corresponding documentation can be equally brief.

Because some psychotic patients do not require antipsychotic medication, or may even become worse on it, patients receiving these drugs on a maintenance basis should be assessed by a psychiatrist at least every 3 months. When the frequency of visits to a psychiatrist is less than once every 3 months, the reasons for the reduced frequency should be noted.

Available evidence indicates that the routine blood counts or blood biochemistry analyses for patients on maintenance antipsychotics have virtually no value in predicting serious adverse effects. The exception is the atypical antipsychotic clozapine, with which the risk of agranulocytosis necessitates weekly white blood cell count monitoring for the first 18 weeks, then monthly.

### Inpatient and outpatient criteria

*Review if:*

absent	A.	<u>Common indications:</u>
		1 Schizophrenia
		2 Delusional disorders
		3 Schizoaffective disorders
		4 Schizophreniform disorder, brief reactive psychosis or disorder not otherwise specified (NOS)
psychotic		5 Bipolar disorder manic or mixed
		6 Major depressive episode with psychotic features
		7 Organic mental syndrome with psychotic features
		8 Tourette's syndrome
		9 Aggressive/disruptive behaviour in delirious, dementing or mentally retarded patients (low doses)
absent requirements)	B.	<u>Minimal documentation</u> (all standard inpatient or outpatient requirements)

absent lower C. Dosage range (see table). Starting doses, in most cases, will be than the minimum indicated. (note that dosage should be less in the elderly)

Generic name	Dose
Chlorpromazine	200-1000 mg
Thioridazine	100-800 mg*
Pericyazine	5-75 mg
Fluphenazine hydrochloride (oral)	5-20 mg
Fluphenazine decanoate (depot)	12.5-100 mg/fortnight IMI
Perphenazine	8-64 mg
Trifluoperazine	10-50 mg
Flupenthixol decanoate	20-200 mg/fortnight IMI
Thiothixene	10-40 mg
Haloperidol (oral)	0.5-20 mg
Haloperidol decanoate (depot)	25-300 mg/month IMI
Pimozide	2-10 mg +

\* upper dose related to increased risk of retinitis pigmentosa

+ cardiotoxic above 20 mg daily

present period D. Duration:

- 1 More than two changes of antipsychotic in any seven day
- 2 More than 3 months in non-psychotic disorders

present E. Concomitancy:

- 1 Any other antipsychotic drug
- 2 More than two other concomitant psychotropic drugs

present F. Critical adverse developments:

- 1 Marked sedation or lethargy after one week
- 2 Urinary retention
- 3 Syncope
- 4 Extrapyramidal effects (e.g. dystonia, akathisia)
- 5 Convulsion
- 6 Tardive dyskinesia
- 7 Neuroleptic malignant syndrome
- 8 Any follow-up laboratory abnormalities during treatment, for example:
  - a. bilirubin > 2mg
  - b. serum glutamic pyruvic transaminase (SGPT) > 100 IU/ml
  - c. white cell count < 3,000
- 9 Intentional overdose

absent G. Critical adjunctive services:

- 1 Basic laboratory studies on admission
- 2 ECG on admission if history or physical examination suggestive of cardiac disorder

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3 Examination for tardive dyskinesia (every 3-6 months)

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present	H.	<u>Relative contraindications:</u>
	1	History of allergy or hypersensitivity to the drug
	2	Myocardial infarction within 6 weeks
	3	History of tardive dyskinesia
	4	Age less than 12 years
	5	History of agranulocytosis
	6	History of neuroleptic malignant syndrome
	7	Pregnancy or breast feeding

## B. Atypical antipsychotics

### i) Clozapine

Clozapine is a newly introduced atypical antipsychotic agent. It has strict prescribing guidelines because of the risk of agranulocytosis. Its use should be limited to schizophrenic patients who are non-responsive to, or intolerant of classical neuroleptic drug treatment, who have a normal white blood count and differential blood count and in whom regular white cell counts can be performed (weekly during the first 18 weeks, at least monthly thereafter as long as treatment continues).

Non-responsiveness is defined as lack of satisfactory clinical improvement despite the use of adequate doses (the equivalent of at least 600 mg chlorpromazine daily) of at least two different classes of neuroleptics for adequate durations.

Intolerance is defined as the inability to achieve adequate benefit with classical neuroleptic drugs because of severe and untreatable adverse reactions.

### Inpatient and outpatient criteria

Review if:

absent	A.	<u>Common indications:</u>
	1	Treatment-resistant schizophrenia
absent	B.	<u>Minimal documentation:</u>
two appropriate drugs, either achieve an those drugs.	1	For clozapine, there should be documentation of failure to respond adequately to treatment with at least courses of different classes of standard antipsychotic because of insufficient effectiveness or the inability to effective dose due to intolerable adverse effects from
absent	C.	<u>Dose range:</u>
	1	200-600 mg/day; the usual starting dose is 25 mg/day (note that dosage should be less in the elderly)
present	D.	<u>Duration</u>
	1	Less than 3 days

		2	More than two changes of psychotropic medication in any seven day period
present	E.		<u>Concomitancy:</u>
		1	Any drug associated with a substantial potential for causing agranulocytosis e.g. carbamazepine, non-steroidal inflammatory drugs, sulphonamides
anti-		2	Any other antipsychotic drug; especially depot preparations
		3	Any other concomitant psychotropic drugs
		4	Drugs with anticholinergic, hypotensive or respiratory effects e.g. irreversible (traditional) MAO inhibitors, benzodiazepines, sedative antihistamines, narcotics
depressant alcohol,		5	Highly protein bound drugs e.g. warfarin
present	F.		<u>Critical adverse developments:</u>
		1	Granulocytopaenia i.e. $WBC < 3.0 \times 10^9$ and/or neutrophils $< 1.5 \times 10^9/L$ MUST STOP CLOZAPINE IMMEDIATELY AND NEVER
RESUME		2	Symptoms of agranulocytosis e.g. sore throat, fever
		3	Serial fall in WBC of $> 1.5 \times 10^9/L$ and/or neutrophils of $0.5 \times 10^9/L$
		4	$WBC < 3.5 \times 10^9/L$ and/or neutrophils $< 2.0 \times 10^9/L$
		5	Convulsion
		6	Syncope
		7	Hypertension, ECG changes, arrhythmias or myocarditis
		8	Circulatory collapse
		9	Urinary retention or incontinence
		10	Priapism
		11	Disturbance in temperature regulation
		12	Neuroleptic malignant syndrome
		13	Rigidity, tremor or akathisia
		14	Any follow-up laboratory abnormalities during treatment, for example: a bilirubin $> 2$ mg b serum glutamic pyruvic transaminase (SGPT) $> 100$ IU/ml
		15	Intentional overdose
absent	G.		<u>Critical adjunctive services:</u>
		1	Weekly WBC count
		2	Basic laboratory studies on admission
		3	ECG on admission
		4	Examination for tardive dyskinesia (every 3-6 months)
present	H.		<u>Contraindications:</u>
		1	$WBC < 3.0 \times 10^9/L$ and/or neutrophils $< 1.5 \times 10^9/L$ before commencing clozapine (absolute)
		2	History of drug-induced granulocytopaenia/ agranulocytosis (absolute)

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cause	3	Circulatory collapse and/or CNS depression due to any (absolute)
	4	Previous hypersensitivity to clozapine (absolute)
	5	Alcoholic and other toxic psychoses
	6	Severe hepatic, renal or cardiac disease
	7	Myocardial infarction within 6 weeks
	8	Epilepsy
	9	Age less than 15 years
	10	History of neuroleptic malignant syndrome
	11	Pregnancy or breast feeding

**ii) Risperidone**

Risperidone is a serotonin-dopamine antagonist. It reduces both the positive and negative symptoms of schizophrenia. It has fewer extrapyramidal effects, but potent alpha-1 adrenergic antagonism produces the likelihood of postural hypotension if the dose is not introduced slowly. In patients with liver insufficiency the unbound fraction is increased, so that the initial dose and subsequent increases need to be smaller. Care should be taken in the elderly and those with renal insufficiency, in whom plasma concentrations are higher than normal. It should be used with caution in combination with other centrally acting drugs. Risperidone has a bell dose response curve, and in the majority of patients, 6 mg is the optimum daily dose. Doses above 5 mg BD have not been shown to be superior in efficacy to lower doses and may cause EPS.

**Inpatient and Outpatient Criteria**

absent	A.	<u>Common Indications</u>
		1 Schizophrenia
		2 Delusional disorders
		3 Schizoaffective disorders
psychotic		4 Schizophreniform disorder, brief reactive psychosis or disorder not otherwise specified (NOS)
absent	B.	<u>Minimal documentation</u> (all standard inpatient or outpatient requirements)
absent	C.	<u>Dosage range</u>
BD		1 4-8 mg per day as a twice daily dose. It is essential to commence with a dose no higher than 1 mg and increase the dose gradually due to the risk of postural hypotension. Lower starting and incremental doses used in the elderly, and those with renal or liver impairment. In most patients 3 mg BD is the optimal dose
present	D.	<u>Duration</u>
		1 More than two changes of antipsychotic in any 7-day period
present	E.	<u>Concomitancy</u>
		1 Any other antipsychotic drug
		2 More than two other concomitant psychotropic drugs



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present	F.	<u>Critical adverse developments</u>
		1 Orthostatic hypotension
		2 Marked sedation or lethargy after one week
		3 Syncope
		4 Extrapyrarnidal effects (eg dystonia, akathisia)
		5 Convulsion
		6 Tardive dyskinesia
		7 Neuroleptic malignant syndrome
		8 Any follow-up laboratory abnormalities during treatment, for example:
		a. bilirubin > 2 mg
		b. serum glutamic pyruvic transaminase (SGPT) > 100 IU/ml
		c. white cell count < 3,000
		9 Intentional overdose
absent	G.	<u>Critical adjunctive services</u>
		1 Basic laboratory studies on admission
history of		2 ECG on admission for patients over 65 years of age or if cardiac disorder
		3 Examination for tardive dyskinesia (every 3-6 months)
present	H.	<u>Relative contraindications</u>
		1 History of allergy or hypersensitivity to the drug
		2 Myocardial infarction within 6 weeks
		3 History of tardive dyskinesia
		4 Age less than 15 years
		5 History of agranulocytosis
		6 History of neuroleptic malignant syndrome
		7 Pregnancy or nursing

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## 6. Antiparkinsonian Medications

There is a clear consensus that many patients who receive antiparkinsonian medications early in the course of antipsychotic drug therapy do not need continued antiparkinsonian medication after a maintenance level of the antipsychotic has been established. The 3 months review criterion (criterion D1 "Duration") was established with the view that by that time, the patient should have had a trial off the medication. However, the patient should be carefully evaluated for subtle dyskinesia and akathisia when antiparkinsonian drugs are withdrawn. These side effects may continue to occur and are frequently inadequately diagnosed and treated.

### Inpatient and outpatient criteria

*Review if:*

absent	A.	<u>Common indications:</u>	
		1	Alleviation of extrapyramidal side effects (EPSE) induced by antipsychotic drugs
absent	B.	<u>Minimal documentation</u> (all standard requirements):	
		1	Should include a statement that patient has developed EPSE after the antipsychotic drug was initiated or that the antiparkinsonian drug was begun prophylactically with an antipsychotic
absent	C.	<u>Dosage range:</u>	
		<b>Generic name</b>	<b>Dose</b>
		Benztropine	0.5-6 mg
		Orphenadrine hydrochloride	100-300 mg
		Procyclidine	6-20 mg
		Benzhexol hydrochloride	2-15 mg
		Biperiden	2-8 mg
present	D.	<u>Duration:</u>	
		1	Over 3 months
present	E.	<u>Concomitancy:</u>	
		1	Any other anticholinergic medication (except antipsychotic)
		2	More than two other concomitant psychotropic drugs
present	F.	<u>Critical adverse developments:</u>	
		1	Urinary retention
		2	Severe constipation
		3	Delirium or confusion
		4	Anticholinergic toxicity

- 
- absent            G.    Critical adjunctive services (inpatient only):
- 1        Basic laboratory studies on admission
  - 2        Renal function laboratory studies for patients receiving amantadine
- present           H.    Relative contraindications:
- 1        History of hypersensitivity to this class of drug
  - 2        Narrow angle glaucoma (except            for amantadine)
  - 3        Prostatic hypertrophy (except for amantadine)
  - 4        Age less than 7 years
  - 5        Pregnancy

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## 7. Mood Stabilisers

### A. Lithium

For patients on lithium therapy, tests of renal and thyroid function are recommended before commencing treatment, and at least every 6-12 months or more frequently if clinically indicated. Determination of the serum lithium level is recommended every 5-7 days until stabilised, and then at a minimum of every 3 months for well-stabilised adults and a minimum of every 2 months for children under 16 years. Pregnancy and breast-feeding are considered to be relative contraindications to lithium use because of the possibility of fetal cardiovascular malformations, as well as the appearance of lithium in breast milk. Concomitant use of lithium and an antipsychotic medication for acute mania may be useful, but lithium alone is preferable for maintenance treatment. The combination of lithium and an antidepressant may be appropriate when a satisfactory response cannot be obtained with either drug alone. For patients under the age of 16 years, thyroid studies are recommended every 4 months.

#### Inpatient and outpatient criteria

*Review if:*

absent	A.	<u>Common indications:</u>
treatment or	1	Bipolar disorder mixed, manic or depressed - acute long-term prophylaxis
	2	Schizoaffective disorder
	3	Bipolar disorder NOS
	4	Cyclothymia
	5	Major depression, recurrent, for maintenance treatment or adjunct for acute treatment
absent requirements)	B.	<u>Minimal documentation</u> (all standard inpatient or outpatient requirements)
absent	C.	<u>Dosage range:</u>
same	1	Oral dosage: 500-2,000 mg daily. Serum concentration: acute treatment 0.8-1.4 mmol/L; maintenance treatment 0.6-1.0 mmol/L (note that dosage may be less in the elderly to achieve the same serum concentration)
present	D.	<u>Duration:</u>
	1	Less than 3 days
	2	More than two changes of psychotropic medication in any 7-day period
present	E.	<u>Concomitancy:</u>
	1	Diuretic medication
	2	Salt-free diet
	3	Non-steroidal anti-inflammatory drugs
	4	Theophylline
	5	More than two other psychotropic drugs of any class

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present	F.	<u>Critical adverse developments:</u>
		1 Lethargy, stupor, or coma
		2 Polyuria and polydipsia
		3 Severe tremor
		4 Vomiting
		5 Nausea or diarrhoea
		6 Ataxia and dysarthria
		7 Significant change in renal function tests
		8 Significant change in thyroid function
		9 Intentional overdose
absent	G.	<u>Critical adjunctive services:</u>
		1 Basic laboratory studies on admission (and at initiation of lithium for outpatients) including measures of renal and thyroid function.
		2 ECG for patients under 16 years and over 65 years
		3 Serum electrolytes on admission
		4 Measurement of plasma lithium level at least twice in the first 10 days of treatment and at least every 3 months during maintenance treatment (every 2 months for children under 16 years)
		5 Laboratory tests for thyroid and renal function at least every 6 months during maintenance therapy (at least every 4 months for patients under 18 years)
present	H.	<u>Relative contraindications:</u>
		1 History of adverse reaction to this drug or abnormal renal function tests
		2 Renal failure
		3 Vomiting
		4 Dehydration
		5 Blood urea nitrogen (BUN) above 8 mmol/L or serum creatinine above 0.12 mmol/L
		6 Age less than 12 years
		7 Pregnancy (particularly first trimester) or breast feeding
		8 Hypothyroidism

## **B. Anticonvulsants**

Anticonvulsants are being increasingly used in the treatment of bipolar disorder both for acute mania and in long-term prophylaxis. They are usually indicated when patients are either unresponsive to, or unable to tolerate, lithium.

Determination of serum anticonvulsant levels is recommended at a minimum of every 3 months for well-stabilised adults and a minimum of every 2 months for children under 16 years. Concomitant use of anticonvulsants and an antipsychotic medication for acute mania may be useful, but anticonvulsants alone are preferable for maintenance treatment. The combination of anticonvulsants and an antidepressant and/or with lithium carbonate, may be appropriate when a satisfactory response cannot be obtained with either drug alone.

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**i) Carbamazepine - Inpatient and outpatient criteria**

Review if:

absent	A.	<u>Common indications:</u>
treatment or	1	Bipolar disorder mixed, manic or depressed - acute long-term prophylaxis
	2	Schizoaffective disorder
	3	Epilepsy
absent requirements)	B.	<u>Minimal documentation</u> (all standard inpatient or outpatient requirements)
absent	C.	<u>Dosage range:</u> (note that dosage may be less in the elderly to achieve the same serum concentrations)
	1	Oral dosage: 600-1,500 mg daily. Serum concentration: 20-50 micromol/L
present	D.	<u>Duration:</u>
	1	Patient on carbamazepine less than 3 days
	2	More than two changes of psychotropic medication in any seven day period
present	E.	<u>Concomitancy:</u>
	1	More than two other psychotropic drugs of any class
	2	Other anticonvulsants
present	F.	<u>Critical adverse developments:</u>
	1	Vomiting/nausea
	2	Ataxia and dysarthria
	3	Intentional overdose
	4	Sedation, vertigo, diplopia
	5	Rash
	6	Leucopenia
	7	Elevated liver function tests/hepatic failure
	8	Thrombocytopaenia
absent	G.	<u>Critical adjunctive services:</u>
electrolytes	1	Basic laboratory studies on admission including full blood count, liver function tests, serum creatinine and
the	2	Measurement of serum carbamazepine level at least twice in first 10 days of treatment, at one month after initiation of therapy and at least every 3 months during maintenance treatment
	3	Laboratory tests: Full blood count, liver function, serum electrolytes at least each month for the first two months, then each six months thereafter

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present	H.	<u>Relative contraindications:</u>
	1	History of adverse reaction to this drug or abnormal renal function tests
	2	Pregnancy or breast feeding
	3	Bone marrow suppression
	4	Hepatic impairment
	5	Atrioventricular block

**ii) Sodium valproate - Inpatient and outpatient criteria**

*Review if:*

absent	A.	<u>Common indications:</u>
treatment or	1	Bipolar disorder mixed, manic or depressed - acute long-term prophylaxis
	2	Schizoaffective disorder
	3	Epilepsy

absent requirements)	B.	<u>Minimal documentation</u> (all standard inpatient or outpatient requirements)
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absent	C.	<u>Dosage range:</u>
same	1	Oral dosage: 500-2,000 mg daily. Serum concentration: 350-700 micromol/L (note that dosage may be less in the elderly to achieve the serum concentration)

present	D.	<u>Duration:</u>
	1	Patient on valproate less than 3 days
	2	More than two changes of psychotropic medication in any seven day period

present	E.	<u>Concomitancy:</u>
	1	More than two other psychotropic drugs of any class
	2	Other anticonvulsant medications

present	F.	<u>Critical adverse developments:</u>
	1	Lethargy, stupor, or coma
	2	Vomiting
	3	Nausea or diarrhoea
	4	Ataxia, tremor, incoordination
	5	Significant change in liver function tests/hepatic failure
	6	Intentional overdose

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absent	G.	<u>Critical adjunctive services:</u>
		1 Basic laboratory studies on admission including liver and renal function tests and full blood count
during		2 Measurement of plasma valproate level at least twice in the first 10 days of treatment and at least every 3 months maintenance treatment
		3 Laboratory tests for liver function at least monthly for the first 6 months during maintenance therapy
present	H.	<u>Relative contraindications:</u>
		1 History of adverse reaction to this drug or abnormal renal function tests
		2 Pregnancy or breast feeding
		3 Pre-existing hepatic dysfunction

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## 8. Antidepressants

Antidepressants are now considered to be indicated for the treatment of unipolar and bipolar depression, panic disorder, agoraphobia, social phobia, obsessive-compulsive disorder, and some other psychiatric and medical conditions. Tricyclic antidepressants may exacerbate some pre-existing cardiac conduction deficits, therefore, for individuals at risk, electrocardiograms should be done at appropriate intervals.

Antidepressants should be used with caution in children and adolescents since their efficacy in non-psychotic depression has not yet been demonstrated. In the elderly lower doses may be required because of slower metabolism of some drugs, and increased sensitivity to adverse effects.

With regard to the use of the irreversible monoamine oxidase (MAO) inhibitors, the medical record should have a notation to the effect that the patient was informed concerning the nature and importance of a low tyramine diet, as well as of potentially toxic drug interactions. The MAO inhibitors are listed for the same indications as the other antidepressant medications. In many situations, the MAO inhibitors would be considered a second-line treatment. There has been very little experience with the use of MAO inhibitors in children under the age of 12 years, so they are included under relative contraindications for review purposes.

The newer antidepressants, i.e. fluoxetine, mianserin and moclobemide are listed separately because of their distinct actions and side-effects. Although no more effective than the tricyclics and irreversible MAOIs, they have the advantages of minimal cardiotoxic effects and greater safety in overdose.

### A. Tricyclic antidepressants - inpatient and outpatient criteria

*Review if:*

absent	A.	<u>Common indications:</u> <ol style="list-style-type: none"><li>1 Bipolar disorder, depressed</li><li>2 Major depression, single episode or recurrent</li><li>3 Dysthymia</li><li>4 Depressive disorder NOS</li><li>5 Panic disorder with or without agoraphobia</li><li>6 Enuresis</li><li>7 Obsessive-compulsive disorder (e.g. clomipramine)</li><li>8 Somatoform pain disorder</li><li>9 Bulimia nervosa</li></ol>
absent requirements)	B.	<u>Minimal documentation</u> (all standard inpatient or outpatient requirements)
absent	C.	<u>Dosage range</u> for adults (half of standard dose if patient over 65 years of age). Starting dose, in most cases, will be lower than the minimum indicated. Plasma levels may be useful for determining the appropriate dosage, particularly for nortriptyline (200-650 nmol/L)
		<ol style="list-style-type: none"><li>1 100-300 mg/day (ages 5-12 years: 25-150 mg daily)</li><li>2 Nortriptyline only: 50-150 mg/day (ages 5-12 years: 10-100 mg daily)</li></ol>



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present	D.	<u>Duration:</u>
	1	Less than 3 days
	2	More than two changes of psychotropic medication in any seven day period
present	E.	<u>Concomitancy:</u>
	1	Any other tricyclic antidepressant/ SSRI/ mianserin
	2	Monoamine oxidase inhibitor (irreversible or reversible)
	3	More than two other psychotropic medications of any class
	4	Guanethidine, clonidine, or bethanidine
	5	Anticholinergic, antiparkinsonian drug
	6	Reserpine
present	F.	<u>Critical adverse developments:</u>
	1	Marked sedation or lethargy after first week
	2	Urinary retention
	3	Syncope
	4	Intentional overdose
	5	Psychosis, hallucinosis, or delirium developing during
treatment	6	Manic symptoms (hyperactivity, euphoria, irritability, etc.) developing during treatment
	7	Clinical significant ECG changes
	8	Accident e.g. fall or motor vehicle accident
	9	Glaucoma
absent	G.	<u>Critical adjunctive services:</u>
	1	Basic laboratory studies on admission
	2	Electrocardiogram on admission if history or physical examination suggestive of cardiovascular disease
	3	For children below age 16 years, ECG at baseline and full dose
again at	4	For children below age 12 years, ECG at baseline, prior to
to		reaching a 3.5-mg/kg dose, and again at full dose
present	H.	<u>Relative contraindications:</u>
	1	History of allergy to this drug
	2	Myocardial infarction within 6 weeks
	3	History of acute angle glaucoma
	4	Pregnancy or breast feeding
	5	Children less than 4 years of age
	6	Glaucoma
	7	Prostatic hypertrophy
	8	Hypotension

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**B. Selective serotonin reuptake inhibitors (SSRIs) i.e. fluoxetine, paroxetine, sertraline - inpatient and outpatient criteria**

*Review if:*

- absent      A.      Common indications:
- 1      Bipolar disorder, depressed
  - 2      Major depression, single episode      or recurrent
  - 3      Obsessive-compulsive disorder
  - 4      Dysthymia
- absent requirements)      B.      Minimal documentation (all standard inpatient or outpatient requirements)
- absent      C.      Dosage range for depression\*
- | Generic name | Dosage        |
|--------------|---------------|
| Fluoxetine   | 20-80 mg/day  |
| Paroxetine   | 20-50 mg/day  |
| Sertraline   | 50-200 mg/day |
- \* for obsessive compulsive disorder higher doses are often required
- present      D.      Duration:
- 1      Less than 3 days
  - 2      More than two changes of psychotropic medication in any seven day period
- present      E.      Concomitancy:
- 1      Monoamine oxidase inhibitor
  - 2      More than two other psychotropic medications of any class
  - 3      Irreversible MAOI has been commenced within 5 weeks of cessation of fluoxetine
  - 4      SSRI commenced within two weeks of the cessation of an irreversible MAOI
  - 5      Warfarin
  - 6      Tricyclic antidepressant
- present      F.      Critical adverse developments:
- 1      Intentional overdose or other means of suicide attempt
  - 2      Psychosis, hallucinosis, or delirium developing during treatment
  - 3      Manic symptoms (hyperactivity, euphoria, irritability, etc.) developing during treatment
  - 4      Rash
  - 5      Urticaria
  - 6      Other allergic phenomena
  - 7      Severe agitation/akathisia
- absent      G.      Critical adjunctive services:

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1 Basic laboratory studies on admission

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present H. Relative contraindications:

- 1 History of allergy to this drug
- 2 Pregnancy or breast feeding
- 3 Children

**C. Mianserin - Inpatient and outpatient criteria**

*Review if:*

absent A. Common indications:

- 1 Bipolar disorder, depressed
- 2 Major depression, single episode or recurrent
- 3 Dysthymia

absent B. Minimal documentation (all standard inpatient or outpatient requirements)

absent C. Dosage range for adults 30-120 mg.

present D. Duration:

- 1 Less than 3 days
- 2 More than two changes of psychotropic medication in any seven day period

present E. Concomitancy:

- 1 Tricyclic antidepressant/SSRI
- 2 Monoamine oxidase inhibitor (irreversible or reversible)
- 3 More than two other psychotropic medications of any class

present F. Critical adverse developments:

- 1 Marked sedation or lethargy after first week
- 2 Intentional overdose
- 3 Psychosis, hallucinations, or delirium developing during treatment
- 4 Manic symptoms (hyperactivity, euphoria, irritability, etc.) developing during treatment
- 5 Neutropaenia/agranulocytosis/ thrombocytopaenia
- 6 Polyarthrititis
- 7 Falls or accidents

absent G. Critical adjunctive services:

- 1 Basic laboratory studies on admission
- 2 Baseline full blood count

present H. Relative contraindications:

- 1 History of allergy to this drug
- 2 Pregnancy or breast feeding

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3 Children

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**D. Monoamine oxidase inhibitors**

**i) Irreversible monoamine oxidase inhibitors (i.e. phenelzine, tranylcypromine) - inpatient and outpatient criteria**

*Review if:*

absent	A.	<u>Common indications:</u> <ol style="list-style-type: none"><li>1 Bipolar disorder, depressed</li><li>2 Major depression, single episode or recurrent</li><li>3 Dysthymia</li><li>4 Panic disorders, with or without agoraphobia</li><li>5 Social phobia</li></ol>
absent	B.	<u>Minimal documentation</u> (All standard inpatient or outpatient requirements, plus documentation of advice to patient concerning interactions with food and other drugs)
absent	C.	<u>Dosage range:</u> (note that dosage should be less in the elderly) <ol style="list-style-type: none"><li>1 Phenelzine: 30-90 mg per day</li><li>2 Tranylcypromine: 30-60 mg pe day</li></ol>
present	D.	<u>Duration:</u> <ol style="list-style-type: none"><li>1 Less than 3 days</li><li>2 More than two changes of psychotropic medication in any seven day period</li></ol>
present	E.	<u>Concomitancy:</u> <ol style="list-style-type: none"><li>1 Any other monoamine oxidase inhibitor</li><li>2 Any other antidepressant</li><li>3 Fluoxetine within previous 5 weeks</li><li>4 Pethidine</li><li>5 Reserpine</li><li>6 Any psychostimulant</li><li>7 Any drug containing adrenaline or its congeners</li><li>8 More than one other psychotropic medication of any class</li><li>9 Diet containing tyramine</li></ol>
present	F.	<u>Critical adverse developments:</u> <ol style="list-style-type: none"><li>1 Marked sedation or lethargy</li><li>2 Agitation, restlessness</li><li>3 Confusion</li><li>4 Severe headache</li><li>5 Coma</li><li>6 Intentional overdose</li><li>7 Psychosis, hallucinosis, or delirium developing during treatment</li><li>8 Manic symptoms (hyperactivity, euphoria, irritability, etc.) developing during treatment</li></ol>

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		9	Accident e.g. fall, motor vehicle accident
		10	Significant hypertension or hypotension
absent	G.	<u>Critical adjunctive services:</u>	
		1	Laboratory studies on admission
		2	ECG for patients over 40 years of age
		3	Tyramine-restricted diet
present	H.	<u>Relative contraindications:</u>	
		1	Known hypersensitivity to these drugs
		2	Myocardial infarction within 6 weeks
		3	Age less than 12 years without frequent electrocardiograms
		4	Pregnancy or breast feeding
		5	Inability to comply with dietary restrictions

**ii) Reversible monoamine oxidase inhibitor, i.e. moclobemide  
- inpatient and outpatient criteria**

*Review if:*

absent	A.	<u>Common indications:</u>	
		1	Bipolar disorder, depressed
		2	Major depression, single episode or recurrent
		3	Dysthymia
absent requirements)	B.	<u>Minimal documentation</u> (all standard inpatient or outpatient requirements)	
absent	C.	<u>Dosage range:</u> 300-600 mg (dosage may need to be less in the elderly)	
present	D.	<u>Duration:</u>	
		1	Less than 3 days
		2	More than two changes of psychotropic medication in any seven day period
present	E.	<u>Concomitancy:</u>	
		1	Any other monoamine oxidase inhibitor
		2	Any other non-MAOI antidepressant
		3	More than one other psychotropic medication of any class
		4	Pethidine
		5	Cimetidine (impairs the metabolism of moclobemide, producing increased levels)
		6	Fluoxetine within last 2 weeks

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present	F.	<u>Critical adverse developments:</u>
		1 Agitation, restlessness
		2 Confusion
		3 Intentional overdose
		4 Psychosis, hallucinosis, or delirium developing during treatment
		5 Manic symptoms (hyperactivity, euphoria, irritability, etc.) developing during treatment
absent	G.	<u>Critical adjunctive services:</u>
		1 Laboratory studies on admission
present	H.	<u>Relative contraindications:</u>
		1 Known hypersensitivity to this drug
		2 Acute confusional states
		3 Children
		4 Pregnancy or breast feeding

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## 9. Stimulants

The major use of stimulants in psychiatry is for attention deficit hyperactivity disorder. It is also used in the rare condition of narcolepsy. There have been reports of the use of stimulants for the treatment of depression (usually combined with tricyclic antidepressant medications) but this is not regarded as a normal criterion for use, and is not included here. Their use in the treatment of obesity is not a valid indication.

### Inpatient and outpatient criteria

*Review if:*

absent	A.	<u>Common indications:</u>
		1 Attention deficit hyperactivity disorder
		2 Undifferentiated attention deficit disorder
		3 Narcolepsy
absent	B.	<u>Minimal documentation:</u>
absent	C.	<u>Dosage range:</u>
		1 Dextroamphetamine: 5-40 mg daily (children: 0.1 to 0.5 mg/kg once or twice daily)
		2 Methylphenidate: 10-60 mg daily (children: 0.1 to 0.5 mg/kg once or twice daily)
present	D.	<u>Duration:</u>
		1 More than two changes of psychotropic medication in any seven day period
present	E.	<u>Concomitancy:</u>
		1 More than one other psychotropic medication
		2 Monoamine oxidase inhibitors
present	F.	<u>Critical adverse reactions:</u>
		1 Palpitations, tachycardia (over 120 bpm)
		2 Elevation of blood pressure
		3 Anorexia and weight loss (or for children, less than expected weight gain)
		4 Insomnia
		5 Over-stimulation, restlessness, tremor, dizziness
		6 Psychotic symptoms
		7 Tics or other abnormal involuntary movements
		8 Misery, tearfulness
absent	G.	<u>Critical adjunctive services:</u>
		1 Basic laboratory studies on admission
		2 Height every three months (for patient under 16 years of age)
		3 Weight every three months (for patients under 16 years of age)

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present

H.

Relative contraindications:

- 1 History of allergy or adverse reaction to this drug
- 2 History of drug or alcohol abuse
- 3 Hypertension
- 4 Symptomatic cardiovascular disease
- 5 Hyperthyroidism
- 6 History of psychosis
- 7 Tic disorder or a family history of tics
- 8 Pregnancy and breast feeding
- 9 Age less than five years
- 10 Clinical levels of anxiety

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## 10. Appendix

### Categorisation of risk of drug use in pregnancy

(From 'Medicines in Pregnancy' 2nd Edition. Australian Drug Evaluation Committee: Canberra, 1992)

**Category A:** Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

**Category B:** Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformations or other direct or indirect harmful effects on the human fetus having been observed.

As experience of effects of drugs in this category in humans is limited, results of toxicological studies to date (including reproduction studies in animals) are indicated by allocation of one of three subgroups:

**Group B1:** Studies in animals have not shown evidence of an increased occurrence of fetal damage.

**Group B2:** Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

**Group B3:** Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.

**Category C:** Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible.

**Category D:** Drugs which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human fetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects.



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