

# [Medicine name]<sup>®</sup> *(if phonetic spelling is required, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary).*

Generic name

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## Consumer Medicine Information

Consumer Name  
Consumer Address  
Consumer Address

*Date of Dispensing*

*Pharmacist Name  
Pharmacist Address  
Pharmacist Address*

### What is in this leaflet<sup>1</sup>

This leaflet answers some common questions about [Medicine name].

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking [Medicine name] against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

***Note: The statements in this core document are optional. Some may not be appropriate for a given product. In order to achieve consistency, however, CMI writers are encouraged to use these statements and follow the Second Edition of the Usability Guidelines wherever possible.***

<sup>1</sup> Depending on the length of your CMI, consider using a table of contents (see Second Edition of the Usability Guidelines).

### What [Medicine name] is used for

*Alternatives for the indications section:*

*For those with schizophrenia as the indication:*

[Medicine name] is used to treat / for the long term treatment of schizophrenia. Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour:

*For those with psychoses as the indication:*

[Medicine name] is used to treat mental illnesses with disturbances in thinking, feelings and behaviour:

*Others:*

[Medicine name] is used to treat mental illnesses such as:

- schizophrenia, an illness with disturbances in thinking, feelings and behaviour
- mania, an illness where the patient experiences episodes of overactivity, elation or irritability
- certain types of depression

It is also used to treat:

- behavioural problems in children with mental retardation or mental illness
- nausea and vomiting (caused by cancer treatment)
- anxiety and pain during surgery (*neurolept anaesthesia*)
- hiccoughs that do not stop (*intractable hiccoughs*)

- Tourette's Syndrome, a condition with uncontrolled vocal outbursts and body movements (tics)
- severe anxiety, tension or excitement / severe agitation, hyperactivity or aggression / episodes of overactivity, elation or irritability (mania) in patients with mental or emotional illness

Your doctor may have prescribed [Medicine name] for another reason. Ask your doctor if you have any questions about why [Medicine name] has been prescribed for you.

[Medicine name] belongs to a group of medicines called (*chemical or therapeutic class*). It helps to correct chemical imbalances in the brain, which may cause mental illness. *These chemicals may also affect the parts of the brain which control nausea and vomiting.*

*For depot injections:*

[Medicine name] is given as an injection into a large muscle where it is slowly released over 2 - x weeks. This injection should only be given by a doctor or nurse.

There is no evidence that [Medicine name] is addictive / habit forming.

This medicine is available only with a doctor's prescription.

Use in children statement<sup>2</sup>:

[Medicine name] is not recommended for use in children (under the age of x), as there is not enough information on its effects in children / this age group.

Alternative:

[Medicine name] is not recommended for use in children (under the age of x), as safety and effectiveness have not been established in this age group.

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## Before you take [Medicine name]

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or

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## Before you are given [Medicine name]

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**When you must not take it**  
**When you must not be given it**

(as per PI):

**Do not take [Medicine name] if you have an allergy to:**

- [Medicine name] (*or: generic name, the active ingredient in [Medicine name]*)
- related medicines<sup>3</sup>
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to [Medicine name] may include<sup>4</sup>:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

**Do not take [Medicine name] if you have or have had any of the following medical conditions:**

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<sup>2</sup> Consider this position if use in children is not a contraindication.

<sup>3</sup> Insert the chemical class if previously mentioned under 'What [Medicine name] is used for'.

<sup>4</sup> You may use these symptoms if your PI does not list specific hypersensitivity reactions

- brain damage (*brain damage*)
- kidney disease (*impaired renal function, renal insufficiency*)
- liver disease (*acute liver disease, hepatic failure*)
- yellowing of the skin and/or eyes (jaundice) (*jaundice*)
- heart and blood vessel disease (*cardiovascular insufficiency, cardiovascular disorder, angina*)
- collapse caused by very low blood pressure (*circulatory collapse*)
- fast or irregular heart beat (*arrhythmia*)
- disease of the blood with a reduced number of red / white blood cells / platelets (*blood dyscrasia, bone marrow depression, granulocytopenia, agranulocytosis*)
- low blood pressure (*hypotension*)
- Parkinson's Disease
- epilepsy (that is not controlled) (*epilepsy*)
- spasticity, where a group of muscles are stiff and restricted in movement (*spasticity*)
- phaeochromocytoma, a rare tumour of the adrenal glands which sit near the kidneys (*phaeochromocytoma*)
- alcohol or drug intoxication (*alcoholic and other toxic psychoses*)
- Any other contraindications, as per PI.

**Do not give [Medicine name] to anyone who is unconscious or in a coma.**

If use in children a contraindication:

**Do not give [Medicine name] to a child under x years, unless directed by the child's doctor.**

[Medicine name] is not recommended for use in children under x years.

*Tampering and expiry date warnings:*

**Do not take [Medicine name] after the expiry date (EXP)<sup>5</sup> printed on the pack.**

**Do not take [Medicine name] if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking [Medicine name], talk to your doctor or pharmacist.

**Before you start to take it**  
**Before you are given it**

**Tell your doctor if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

**Tell your doctor if you are pregnant or intend to become pregnant.**

Like most (*chemical / therapeutic class*) medicines, [Medicine name] is not recommended for use during pregnancy. However, if you need to take/be given [Medicine name] during your pregnancy, your doctor will discuss with you the benefits and risks of taking/being given it.

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

It is recommended that you do not breast-feed while taking [Medicine name], as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

*Alternative explanation:*

It is recommended that you do not breast-feed while taking [Medicine name], as it is not known whether [Medicine name] passes into breast milk.

**Be sure you have discussed with your doctor the risks and**

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<sup>5</sup> Only include 'EXP' if that is the abbreviation used on your packaging.

## benefits of using this medicine while breast-feeding.

### If you do decide to breast-feed while taking [Medicine name], watch your baby carefully.

If your baby develops a skin rash, becomes sleepy or has unusual symptoms, don't breast-feed again until you speak to your doctor.

### Tell your doctor if you have or have had any medical conditions, especially the following:

- tumour of the pituitary gland, a small gland at the base of the brain (*pituitary tumour*)
- brain tumour (*brain tumour*)
- kidney problems (*renal insufficiency, renal disease*)
- heart and blood vessel problems (*cardiovascular insufficiency, angina, mitral valve insufficiency, circulatory collapse*)
- fast or irregular heart beat (*arrhythmia, QT prolongation*)
- liver disease (*acute liver disease, hepatic failure*)
- disease of the blood with a reduced number of red / white blood cells / platelets (*blood dyscrasia, bone marrow depression, granulocytopenia, agranulocytosis*)
- prostate problems (*prostatic hypertrophy*)
- breast cancer or a family history of breast cancer (*breast cancer*)
- breathing difficulties (*asthma, emphysema, respiratory infections, silent pneumonia*)
- paralytic ileus, a condition where the small bowel does not work properly (*paralytic ileus*)
- blockage in your intestines (*intestinal obstruction*)
- epilepsy, seizures or fits (*epilepsy*)
- diabetes (*diabetes*)
- low blood pressure (*hypotension*)
- low blood potassium levels (*hypokalaemia*)
- an overactive thyroid gland (*thyrotoxicosis*)
- glaucoma, a condition in which there is usually a build-up of fluid in the eye (*glaucoma*)

- eye problems, such as diseases of the retina or blurred vision (*retinopathy, corneal lesions*)
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions (*neuroleptic malignant syndrome*)
- tardive dyskinesia, a reaction to some medicines with worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaws which may progress to the arms and legs (*tardive dyskinesia*)
- stomach ulcer (*peptic ulcer*)
- *any others, as per PI*

### Tell your doctor if you will be in a hot environment or do a lot of vigorous exercise.

[Medicine name] may make you sweat less, causing your body to overheat.

### Tell your doctor if you are exposed to pesticides which contain phosphorous.

The risk of you experiencing a side effect may be increased.

### If you have not told your doctor or pharmacist about any of the above, tell them before you start taking [Medicine name].

## Taking other medicines

### Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and [Medicine name] may interfere with each other. These include:

- pain killers, including non-steroidal anti-inflammatory drugs (NSAIDs) which are medicines used to relieve pain, swelling and other signs of inflammation
- benzodiazepines and other medicines used to treat anxiety or to help you sleep/for sedation

- antihistamines, medicines used to treat allergies
- anticonvulsants, medicines used to control epilepsy
- medicines used to control depression or mood swings
- antipsychotic medicines, which are used to treat mental illnesses
- medicines used to treat high blood pressure (hypertension)
- medicines used to treat a fast or irregular heart beat (arrhythmia)
- beta-blockers, medicines used to treat angina, high blood pressure, glaucoma and migraine
- medicines used to treat Parkinson's Disease
- anticholinergic medicines, which are medicines used to prevent travel sickness, relieve stomach cramps or treat Parkinson's Disease
- atropine, a medicine which may be used in some eye drops or cough and cold preparations
- some medicines used to prevent blood clots, including warfarin, coumarin and phenindione
- some types of diuretics (fluid tablets), which are medicines used to treat high blood pressure (hypertension) and fluid build-up in your body
- steroid medicines and medicines used as appetite suppressants
- stimulants such as amphetamine
- adrenaline, a medicine used in emergency situations
- some antibiotics, such as erythromycin and rifampicin
- cimetidine, a medicine used to treat stomach ulcers
- bone marrow depressants, medicines which may decrease the number of blood cells produced by your body
- *Any others, as per PI*

These medicines may be affected by [Medicine name], or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Some medicines may interfere with the absorption of [Medicine name]. These include:

- medicines used to treat diarrhoea
- antacids, medicines used to treat stomach ulcers and pain

You can still take these medicines while you are taking [Medicine name]. However, you must take [Medicine name] at least two hours before or two hours after taking any of these medicines to make sure there is no problem with absorption.

*For oral medicines:*

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## How to take [Medicine name]

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*This information will be product specific, consistent with the approved PI. The following order of information is suggested, but will depend upon the particular product and the amount of information. These subheadings and information are suggested but may not be necessary in all cases.*

### Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.**

### How much to take

*Include dosage ranges, usual doses for each indication or patient group.*

Your doctor or pharmacist will tell you how many tablets/capsules you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

### How to take it

*Including taking with water or any other special precautions, if appropriate.*

*Some examples from the Second Edition of the Usability Guidelines:*

[Medicine name]

**Swallow [Medicine name] with a glass of water.**

**Swallow [Medicine name] whole with a full glass of water.**

**Do not chew the tablets/capsules.**

The tablets/capsules have a special coating to stop them dissolving until they have passed through the stomach into the intestines where they work. Chewing them destroys the coating.

*For syrups/suspensions:*

**Shake the bottle well and accurately measure the dose with a medicine measure.**

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can get a medicine measure from your pharmacist.

### When to take it

*Include time with respect to food, dosing intervals, etc.*

**Take [Medicine name] at about the same time each day.**

Taking your tablets/capsules at the same time each day will have the best effect. It will also help you remember when to take the tablets/capsules.

It does not matter if you take [Medicine name] before or after food.

*Alternative instructions:*

**Take [Medicine name] on an empty stomach, for example, 1 hour before food or 2 hours after food.**

Food can interfere with the absorption of [Medicine name].

**Take [Medicine name] during or immediately after a meal, at about the same time each day.**

If you take [Medicine name] on an empty stomach, it may cause stomach upset.

**If you forget to take it**

**If it is almost time for your next dose (within x hours), skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### How long to take it

*Some examples from the Second Edition of the Usability Guidelines:*

**Continue taking the tablets for as long as your doctor tells you.** [Medicine name] helps control your condition, but does not cure it. Therefore you must take [Medicine name] every day.

**Do not stop taking it unless your doctor tells you to - even if you feel better.**

### If you take too much (overdose)

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26)<sup>6</sup>, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much [Medicine name], you may feel ..... (*list symptoms in PI*).

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<sup>6</sup> Consider including the relevant New Zealand telephone numbers here.

*Alternative:*

Symptoms of an overdose to [Medicine name] include some of the side effects listed below (see "Side Effects" section), but are usually of a more severe nature.

*For injections:*

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## How [Medicine name] is given

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*Include dosage ranges, usual doses for each indication or patient group, or a general statement that the dose will depend on the patient and will be determined by the doctor.*

### **How much is given**

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

### **How it is given**

*Some alternatives:*

[Medicine name] is given as an injection into a muscle or as a slow injection into a vein. [Medicine name] should only be given by a doctor, nurse or other trained person.

[Medicine name] is given as a deep injection into a large muscle. It may also be given as an injection under the skin (subcutaneously). [Medicine name] should not be injected directly into the veins (intravenously).

*For depot injections:*

### **How often it is given**

It is recommended that [Medicine name] is given every x weeks, depending on how your body responds to the medicine.

### **How many injections you will need**

[Medicine name]

[Medicine name] helps control your condition, but will not cure it. Therefore, you will need regular injections. Do not miss any injections, even if you feel better.

### **Overdose**

As [Medicine name] is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given [Medicine name], tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention<sup>7</sup>.

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## While you are using [Medicine name]

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### **Things you must do**

*Precautions or warnings as per PI.*

**Tell your doctor immediately if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.**<sup>8</sup>

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking phenothiazine medicines, including [Medicine name].

This condition is more likely to occur during long term treatment with [Medicine name], especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking [Medicine name].**

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<sup>7</sup> The reference to accident and emergency and urgent medical attention could be left out, depending on the type of product.

<sup>8</sup> This section on tardive dyskinesia may be better placed under side effects.

**If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking [Medicine name].**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking [Medicine name].**

**If you become pregnant while taking [Medicine name], tell your doctor (immediately).**

**If you need to have any medical tests while you are taking [Medicine Name], tell your doctor.**

[Medicine Name] may affect the results of some tests.

**Be sure to keep all of your doctor's appointments so that your progress can be checked.**

Your doctor will check your progress and may want to take some blood/eye/skin tests from time to time. This helps to prevent unwanted side effects.

### **Things you must not do**

**Do not give [Medicine name] to anyone else, even if their symptoms seem similar or they have the same condition as you.**

**Do not take [Medicine name] to treat any other complaints unless your doctor tells you to.**

**Do not stop taking [Medicine name], or lower the dosage, even if you are feeling better, without checking with your doctor.**

If you stop taking [Medicine name] suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of [Medicine name] you take each day before stopping completely.

**Do not take any medicines that cause drowsiness while you are taking [Medicine name], unless recommended by your doctor.**

## Things to be careful of

### Be careful driving or operating machinery until you know how [Medicine name] affects you.

As with other anticonvulsant medicines, [Medicine name] may cause dizziness, light-headedness, tiredness, drowsiness (as per PI) in some people. Make sure you know how you react to [Medicine name] before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

### If [Medicine name] makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Getting up slowly may help.

### Be careful when drinking alcohol while taking [Medicine Name].

Combining [Medicine Name] and alcohol can make you more sleepy, dizzy or light-headed<sup>9</sup>. Your doctor may suggest you avoid alcohol while you are being treated with [Medicine name].

### If outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp or tanning bed or booth.

[Medicine Name] may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn. If your skin does appear to be burning, tell your doctor.

### Make sure you keep cool in hot weather and keep warm in cool weather.

[Medicine name] may affect the way your body reacts to temperature changes.

Any other precautions as per PI.

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## Side effects

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<sup>9</sup> You may wish to include this information on alcohol under "Before you take [Medicine name]".

[Medicine name]

The side effects for a particular product will depend on the Product Information and the company's disclosure policy.

Unless listed as a side effect syndrome, side effects should only be listed once.

The following side effects have been listed according to severity. Select those side effects applicable to your product.

### Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking [Medicine name].

[Medicine name] helps most people with (indicated condition), but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Young children / adolescents / the elderly may have an increased chance of getting side effects.

### Ask your doctor or pharmacist to answer any questions you may have.

### Tell your doctor or pharmacist if you notice any of the following and they worry you:

- redness and pain at the injection site
- red, raised skin rash (maculopapular rash)
- blocked nose (nasal stuffiness)
- dry mouth (dry mouth)
- nausea and/or vomiting (nausea, vomiting)
- indigestion (dyspepsia)
- difficulty in speaking and/or swallowing (dysphagia)
- constipation (constipation)
- diarrhoea (diarrhoea)
- stomach or lower back cramps, muscle stiffness (muscle stiffness)
- blurred vision or difficulty focussing (myosis, blurred vision)

- feeling dizzy when standing up (orthostatic hypotension)
- dizziness or spinning sensation (vertigo)
- lack of energy, drowsiness (lethargy, drowsiness, fatigue)
- restlessness, agitation, anxiety, excitement or difficulty concentrating (restlessness, agitation, anxiety, excitement difficulty concentrating, hypomania, hyperactivity, akathisia)
- difficulty sleeping (insomnia)
- excessive dreams (paroniria)
- headache (headache)
- changes in skin colour, pale skin (skin discolouration, pallor)
- hot, dry skin
- increased or decreased sweating
- salivation (salivation)
- extreme thirst (polydypsia)
- weight changes (weight changes)
- increased appetite (increased appetite)
- loss of appetite (anorexia)
- swelling of your hands, feet and ankles (peripheral oedema)
- fluid retention (fluid retention)
- painful, swollen breasts, or breast enlargement in men (breast engorgement, gynacomastia)
- unusual secretion of breast milk (galactorrhoea)
- change in your menstrual periods (menstrual irregularities, menorrhagia, amenorrhoea)
- impaired sexual function in men (impotence, erectile dysfunction, orgasmic dysfunction)
- loss of blood sugar control, including in diabetes (hypoglycaemia, hyperglycaemia)
- list as per PI<sup>10</sup>

These side effects are usually mild.

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<sup>10</sup> List medical terms in brackets after the consumer terminology. The medical terms are not to go into the CMI; rather, they are there to help the CMI writer choose applicable wording for adverse events listed in their PI.

### Alternative explanations:

These are the more common side effects of [Medicine name].

These are the more common side effects of [Medicine name]. Mostly these are mild and short-lived.

**If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:**

- persistent constipation with swollen stomach and vomiting (*atonic colon, adynamic ileus*)
- persistent painful erection (*priapism*)
- rash, itching, hives or flaking, peeling skin (*dermatitis, exfoliative dermatitis, urticaria, skin eruptions*)
- red or purple flat, pinhead spots under the skin (*petechiae*)
- symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which occurs more quickly than normal (*photosensitivity*)
- red, itchy spots which may blister or form raised, red, pale-centered marks (*erythema multiform*)
- yellowing of the skin and/or eyes (*jaundice, cholestatic jaundice, fulminant hepatic necrolysis*)
- changes in colour vision or difficulty seeing at night (*pigmentary retinopathy*)
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers (*agranulocytosis, neutropaenia, leucopaenia*)
- extremely high body temperature (*hyperthermia, fever*)
- worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs (*tardive dyskinesia*)
- sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body (*extrapyramidal symptoms*)

- chills and/or fever (*hyperpyrexia*)
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (*anaemia, haemolytic anaemia*)
- bleeding or bruising more easily than normal (*thrombocytopaenia*)
- difficulty passing urine (*urinary retention*)
- loss of control of your bladder (incontinence) (*urinary incontinence*)
- loss of control of your bowels (*fecal incontinence*)
- frequently passing urine (*polyuria*)
- blood in your urine (*acute interstitial nephritis*)
- fast or irregular heart beat (*arrhythmia, tachycardia*)
- chest pain, which may spread to the neck and shoulders (*chest pain, pericarditis, myocarditis*)
- severe stomach pain that bores through to your back (*pancreatitis*)
- tunnel vision (*acute glaucoma*)
- signs of blood clots, such as sudden severe headache, loss of vision, loss of co-ordination, slurred speech, shortness of breath, chest pain or numbness, heat or swelling in your arms or legs (*thromboembolism*)
- asthma and other breathing difficulties (*asthma, respiratory depression, asphyxia, shortness of breath, failure of the cough reflex*)
- fast breathing (*fast breathing*)
- confusion (*confusion*)
- fainting (*syncope*)
- convulsions, fits or seizures (*epileptoform convulsions*)
- list as per PI

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

**If any of the following happen, do not take your next dose of [Medicine name] before telling your doctor or going to Accident and Emergency at your nearest hospital:**

- sudden signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing (*anaphylaxis*)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (*angioneurotic oedema, laryngeal oedema*)
- severe spasms in the muscles of the shoulders, neck and upper body (*dystonia*)
- sudden increase in body temperature, with sweating, fast heart beat, muscle stiffness and fluctuating blood pressure which may lead to coma (*neuroleptic malignant syndrome*)
- collapse (*circulatory collapse*)
- heart attack (*cardiac arrest*)
- list as per PI

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

**Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

You may notice some side effects after you have finished taking [Medicine name]. The effects of [Medicine name] may last for x days after you have stopped taking it.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.<sup>11</sup>

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## After using [Medicine name]

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*This information will be product specific. See general statements in*

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<sup>11</sup> Consider placing this statement at the beginning of this section.

Second Edition of the Usability Guidelines, including:

## Storage

**Keep your tablets/capsules/ syrup/suppositories in the pack/bottle until it is time to take them.**

If you take the tablets/capsules/ syrup/suppositories out of the pack/bottle they will not keep well.

**Keep your tablets/capsules/ syrup/suppositories in a cool dry place where the temperature stays below x°C.**

**Do not store [Medicine name] or any other medicine in the bathroom or near a sink.**

**Do not leave it in the car on hot days or on window sills.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

*Injections only:*

## Storage

[Medicine name] will be stored by your doctor or pharmacist. The injection is kept in a cool dry place, protected from light, where the temperature stays below x°C.

## Disposal

**If your doctor tells you to stop taking [Medicine name] or the tablets/capsules/ syrup/suppositories has/have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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*This information will be product specific. The Second Edition of the Usability Guidelines suggest the following order:*

[Medicine name]

## What it looks like<sup>12</sup>

### Ingredients

Active ingredients:

- *list actives*

Other ingredients

- *list excipients*

[Medicine name] does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes (*as per your product*).

*Where Australian Food Standard codes exist, these could follow each Australian Approved name.*

### Manufacturer/Distributor/Supplier

*Include:*

- *Name and address of sponsor*
- *AUST R number*
- *Date of preparation*

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<sup>12</sup> Also include tablet scoring etc.