

[Medicine name][®] (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

Consumer Medicine Information

Consumer Name
 Consumer Address
 Consumer Address

Date of Dispensing

Pharmacist Name
Pharmacist Address
Pharmacist Address

What is in this leaflet¹

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.

¹ 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

[Medicine name] is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

For Rivotrol injection:

[Medicine name] is used to control status epilepticus. This is a condition where you experience prolonged or repeated seizures (fits) without any recovery between attacks.

For Zarontin:

[Medicine name] is used to control petit mal (absence) seizures.

For Prominal:

[Medicine name] is used to control grand mal (tonic clonic) and petit mal (absence) seizures.

For all anticonvulsants (as appropriate):

[Medicine name] belongs to a group of medicines called anticonvulsants / antiepileptics / benzodiazepines / barbiturates. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

[Medicine name] is also used to help prevent seizures occurring during or after brain surgery.

[Medicine name] may also be used to treat a rapid or irregular heart beat.

[Medicine name] may also be used to treat sudden, repeated attacks of facial pain, known as trigeminal neuralgia.

[Medicine name] may also be used to control mania, a mental condition with episodes of overactivity, elation or irritability.

[Medicine name] may also be used to prevent bipolar mood disorder where periods of mania² alternate with periods of depression.

[Medicine name] may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may prescribe [Medicine name] in addition to your current therapy when your current treatment is no longer working as well.

Non-approved uses:

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.

² If your drug is not indicated for mania (and therefore the paragraph above is not included), consider inserting the definition for mania here, that is: "a mental condition with episodes of overactivity, elation or irritability"

Statement about addictive properties (for benzodiazepines/ barbiturates):

The use of benzodiazepines/ barbiturates may lead to dependence on the medicine.

Statement about addictive properties (for other anti-convulsants):

There is no evidence that [Medicine name] is addictive.

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

Use in children statement³:

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

Before you take [Medicine name]

or

Before you are given [Medicine name]

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 (as per PI):

- (generic name), the active ingredient in [Medicine name] or any of the ingredients listed at the end of this leaflet
- Tricyclic antidepressants, medicines used to treat depression
- Methylphenobarbitone or any other barbiturate medicines
- other medicines used to treat fits and convulsions

³ Consider this position if use in children is not a contraindication. Will need to test to determine the most appropriate location.

[Medicine name]

Symptoms of an allergic reaction to [Medicine name] may include:

List symptoms as per your PI. If your PI doesn't state specific hypersensitivity symptoms, you may wish to consider the following:

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

Do not take [Medicine name] if you are taking an antidepressant medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.

Taking [Medicine name] with an MAOI, or within 14 days of taking an MAOI, may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

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

- certain types of irregular heart beat (*AV block*)
- lung problems such as difficulty breathing, wheezing and chronic cough (*COAD*)
- (severe) liver disease (*hepatic failure, hepatic dysfunction*)
- a family history of hepatitis, especially when caused by medicines
- a disease of the blood with a reduced number of red or white blood cells or platelets (*anaemia, bone marrow depression*)
- porphyria, a rare blood pigment disorder (*intermittent porphyria, porphyria*)
- Systemic Lupus Erythematosus (*SLE*) (*SLE*)
- a severe skin disorder Steven Johnson's Syndrome
- toxic epidermal necrolysis, a severe skin reaction with painful red areas, which blister and peel
- any others, as per PI

If you are unsure whether any of the above conditions apply to you, ask your doctor.

Do not give [Medicine name] to children who suffer from Attention Deficit Disorder (ADD).

[Medicine name] must not be given to patients addicted to any medicines, drugs of abuse or alcohol.

If pregnancy a contraindication:

Do not take [Medicine name] if you are pregnant or intend to become pregnant, without talking to your doctor first.

Like most anticonvulsant medicines, [Medicine name] is not recommended for use during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take [Medicine name], your doctor can help you decide whether or not to take it during pregnancy.

Alternative explanation:

[Medicine name] may affect your developing baby if you take it during pregnancy.

If breastfeeding a contraindication:

Do not breastfeed while taking [Medicine name].

[Medicine name] passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not take [Medicine name] after the expiry date (EXP)⁴ 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

⁴ Only include 'EXP' if that is the abbreviation used on your packaging.

name], talk to your doctor or pharmacist.

Before you start to take it Before you are given it

Tell your doctor or pharmacist if you have allergies to:

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

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

- heart problems (*cardiac damage*)
- liver problems (*hepatic insufficiency, hepatic damage*)
- kidney problems (*renal damage, renal insufficiency, impaired renal function*)
- kidney stones (*nephrolithiasis, renal calculi*)
- prostate problems (*prostatism*)
- lung problems (*impaired respiratory function*)
- temporarily stopping breathing while you sleep (*sleep apnoea*)
- diabetes (*diabetes*)
- high blood sugar levels (*hyperglycaemia*)
- unsteadiness when walking (*spinal ataxia, cerebellar ataxia*)
- (acute narrow angle) glaucoma (*glaucoma*)
- myasthenia gravis, a condition with drooping eyelids, double vision and difficulty speaking and swallowing, which may be associated with muscle weakness in the arms or legs (*myasthenia gravis*)
- high blood pressure (*hypertension*)
- low blood pressure (*hypotension*)
- lymphadenopathy, a condition of the lymph glands
- mental disorders such as depression or schizophrenia (*depression, schizophrenia*)
- myxedema, a condition where the thyroid gland is underactive, and symptoms include swelling of the face, hands or feet (*myxedema*)

- Systemic Lupus Erythematosus (SLE) (*SLE*)
- porphyria, a rare blood pigment disorder (*porphyria, intermittent porphyria*)
- hypoalbuminaemia, a decrease in serum albumin in the blood, causing water retention (*hypoalbuminaemia*)
- frequent infections such as fever, chills, sore throat or mouth ulcers or a low white blood cell count (*blood dyscrasia with a low white blood cell counts*)
- *Any others, as per PI*

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

[Medicine name] may affect your developing baby if you take it during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take [Medicine name], your doctor can help you decide whether or not to take it during pregnancy.

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

Your doctor will discuss the possible risks and benefits of using [Medicine name] during breastfeeding.

Alternative explanations:

It is recommended that you do not breastfeed 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.

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

If you do breastfeed, watch your baby carefully.

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

If you have not told your doctor or pharmacist about any of the

above, tell them before you start taking [Medicine name].

Optional:

Your doctor may want to test your eyesight before taking [Medicine name] and during the course of your treatment so that any changes in your sight can be detected. In rare cases, patients treated with [Medicine name] have developed problems seeing things that were not directly in front of them.

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:

- MAOIs, medicines used to treat depression
- disulfuram, a medicine used to treat alcoholism
- other medicines used to treat fits and convulsions (such as ... *as per PI*)
- anticoagulants, medicines used to prevent blood clots
- aspirin and other salicylates
- some pain relievers, such as (*as per PI*)
- benzodiazepines, medicines used as sedatives or to treat mental disorders such as anxiety and schizophrenia
- some (other) medicines used to treat mental disorders, such as ... (*as per PI*)
- corticosteroids such as cortisone and prednisolone
- cyclosporin, a medicine used to prevent organ transplant rejection and to treat severe rheumatoid arthritis and some severe skin conditions
- some medicines used to treat cancer, such as (*as per PI*)
- medicines used to treat heart problems, such as (*as per PI*)
- medicines used to treat high blood pressure, such as (*as per PI*)

- some antibiotics and antifungal medicines used to treat infections, such as (*as per PI*)
- isoniazid, a medicine used to prevent and treat tuberculosis (TB)
- some diuretics (fluid tablets), which are medicines used to reduce water retention and high blood pressure
- acetazolamide, a medicine used to reduce water retention and treat glaucoma and some types of seizures
- isotretinoin, a medicine used to treat acne
- some medicines used to treat stomach or duodenal ulcers, such as (*as per PI*)
- antacids, medicines used to treat heartburn or reflux
- metoclopramide, a medicine used to treat nausea and vomiting
- danazol, a medicine used to treat endometriosis
- local anaesthetics, medicines used stop you feeling pain
- general anaesthetics and muscle relaxants, medicines used during an operation
- methadone, a medicine used to control severe pain and to treat heroin addiction
- methylphenidate, a medicine used to treat Attention Defecit Disorder
- tolbutamide and chlorpropamide, medicines used to treat diabetes
- some vitamins such as folic acid, folinic acid, nicotinamide and Vitamin D
- theophylline, a medicine used to treat asthma
- antihistamines, medicines used to prevent or relieve the symptoms of allergies such as hayfever
- sleeping tablets, sedatives and tranquillisers, medicines used to treat mood disorders
- anticholinergic medicines, which are medicines used to prevent travel sickness, relieve stomach cramps or treat Parkinson's Disease
- L-Dopa, a medicine used to treat Parkinson's Disease
- oral contraceptives (birth control pills)

- oestrogens, hormones used in oral contraceptives and in hormone replacement therapy
- *List 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 or pharmacist will advise you.

Your doctor may advise you to use an additional method of contraception while taking [Medicine name].

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking [Medicine name].

How to take [Medicine name]

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.

For oral medicines:

How much to take

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.

Your doctor will tell you how much syrup/how many tablets/capsules/sachet packets you will need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Your doctor may recommend that you start with a low dose of [Medicine name] and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions.

Follow all directions given to you by your doctor 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 to take it

Including taking with water or any other special precautions, if appropriate. Choose which instruction is applicable for your product

Swallow [Medicine name] with a glass of water.

Swallow [Medicine name] whole with a full glass of water. Do not crush or 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.

Chew [Medicine name] tablets before swallowing.

Shake the bottle well and accurately pour the dose with a medicine measure before taking it.

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.

Using the dropper, put x drops of [Medicine name] onto a spoon before taking it. Do not put the drops directly on your tongue from the bottle.

Dissolve the contents of the sachet in water, juice or soft drink just before you plan to take it. Discard any that you have not taken within 24 hours. [Medicine name] will dissolve easily and have no taste or smell.

When to take it

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

Take [Medicine name] at about the same time each day/every morning and every evening.

Taking [Medicine name] at the same time each day will have the best effect. It will also help you remember when to take the tablets/capsules/syrup/sachets.

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

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 you are late for a dose by less than x hours, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If you are late for a dose by more than x hours, skip the dose you missed and take your next dose when you are meant to.

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:

Most anticonvulsant medicines take time to work, so do not be discouraged if you do not feel better straight away. It may take

up to x weeks to feel the full benefit of [Medicine name].

Continue taking [Medicine name] for as long as your doctor tells you to.

[Medicine name] helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.

Do not stop taking [Medicine name], or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping [Medicine name] suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26)⁵, 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 attention⁶.

Symptoms of an overdose with [Medicine name] include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Alternative:

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

For injections:

⁵ Consider including the relevant New Zealand telephone numbers here.

⁶ The reference to accident and emergency and urgent medical attention could be left out, depending on the type of product.

How [Medicine name] is given

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

[Medicine name] is usually given as an injection into your veins.

How many injections you will need

[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 attention⁷.

While you are using [Medicine name]

Things you must do

Precautions or warnings as per PI.

Some examples from the Second Edition of the Usability Guidelines:

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

Tell your doctor immediately if you notice any of the following:

- increase in seizures (fits)
- yellowing of the skin and/or eyes
- swelling of the face
- strong stomach pains
- generally feeling unwell with tiredness, weakness and vomiting

These symptoms may mean that you have a serious condition affecting your liver. You may need urgent medical attention.

Drink plenty of water while taking [Medicine name].

This will help reduce the risk of getting kidney stones.

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

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

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking [Medicine name].

Tell your doctor if you feel [Medicine name] is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken [Medicine name] exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking [Medicine name], tell your doctor.

Tell your doctor if you want to take oral contraceptives while taking [Medicine name].

You may need a higher dose of oral contraceptives than usual to prevent pregnancy, or you may

need to consider other forms of contraception.

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 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 to yours 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 using it unless your doctor tells you to.

Things to be careful of

[Medicine name] may be habit-forming if taken in high doses for a long period of time. Talk to your doctor or pharmacist if you are concerned about this.

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.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

[Medicine name] may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

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

Combining [Medicine Name] and alcohol can make you more sleepy, dizzy or lightheaded. 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.

If you have to test your urine for sugar while taking [Medicine name], make sure your doctor knows which type of test you use.

[Medicine name] may affect the results of some of these tests.

Any other precautions as per PI.

Side effects

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

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 epilepsy/other 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. If you are over 65 years of age you may have an increased chance of getting side effects.⁸

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

If you get any side effects, do not stop taking [Medicine name] without first talking to your doctor or pharmacist.⁹

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

- dizziness or light-headedness (*dizziness, hypotension*)
- feeling tired or drowsy (*fatigue, drowsiness, somnolence*)
- headache (*headache*)
- weakness, unsteadiness when walking, reduced co-ordination or slowed reactions (*muscle weakness, ataxia, decreased co-ordination, slowed reactions*)
- mood changes such as restlessness, agitation, nervousness, irritability or excitement (*restlessness, agitation, nervousness, irritability, paradoxical excitement, emotional lability, transient nervousness, hyperactivity, euphoria*)
- forgetfulness, confusion or loss of concentration (*memory disturbances, confusion, amnesia, decreased concentration, alertness*)
- difficulty speaking or slurred speech (*dysarthria, slurred speech*)
- sleeplessness (insomnia) (*insomnia*)
- indigestion, hiccoughs, stomach pain, cramps or discomfort (*indigestion, hiccoughs, gastric upset,*

abdominal pain, abdominal cramps)

- nausea (feeling sick) or vomiting (*nausea, vomiting*)
- changes in appetite (*anorexia, increased appetite*)
- changes in your weight (*weight gain, weight loss*)
- diarrhoea (*diarrhoea*)
- constipation (*constipation*)
- dry mouth (*dry mouth*)
- bleeding, tender or enlarged gums (*gingival hyperplasia*)
- swollen, red, sore tongue (*glossitis*)
- mouth ulcers and cold sores (*stomatitis*)
- increased saliva (*hypersalivation*)
- change in taste (*taste disturbances*)
- enlargement of facial features including thickening of lips (*coarsening of facial features*)
- coughing and bringing up phlegm (*bronchial hypersecretion, cough*)
- aching joints (*arthralgia*)
- muscle pain or cramps (*muscle pain or cramps*)
- numbness or tingling in hands or feet (*paraesthesia*)
- frequent need to urinate or loss of bladder control (*urinary frequency, incontinence*)
- blurred or double vision, uncontrollable jerky eye movements, difficulty seeing (*blurred vision, diplopia, nystagmus, accommodation disorder, lens opacities*)
- swollen, runny eyes (*conjunctivitis*)
- ringing or buzzing in the ears or other changes in your hearing (*tinnitus, hyperacusis, hypoacusis, change in pitch perception*)
- pain or redness at the injection site (*pain or redness at the injection site*)
- raised red skin rash or itchy skin rash (*measles-like rash, pruritis, urticaria, skin rash*)
- acne (*acne*)
- change in skin colour (*skin pigmentation*)
- sweating (*sweating*)
- excessive hairiness, especially in women (*hirsutism*)
- hair loss (*hair loss*)

- sexual disturbances, such as change in sex drive, impotence, painful erection, early puberty in children (*sexual disturbances, impotence, male infertility, loss of libido, increased sex drive, Peyronie's Disease, reversible early puberty*)
- breast enlargement in men (*gynaecomastia*)
- unusual secretion of breast milk (*galactorrhoea*)
- list as per PI¹⁰

These side effects are usually mild.

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.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- more frequent or more severe seizures (fits) (*increase in seizures*)
- sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body (*abnormal involuntary movements, tremor, asterixis, orofacial dyskinesia, choreoathetoid disorder, dystonias, tics, oculomotor disturbances*)
- severe depression, thoughts of suicide, aggressive behaviour, recurrence of a previous mental illness, or seeing or hearing things that are not there (*depression, suicidal thoughts, aggressive behaviour, activation of psychoses, visual or acoustic hallucinations*)
- fever, sore throat, swollen glands, mouth ulcers, unusual bleeding or bruising under the

⁸ Some medicines might need the preceding statement concerning the increased risk of side effects in the elderly.

⁹ Consider using this statement for products that have withdrawal symptoms on abrupt cessation.

¹⁰ 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.

- skin (*leucopenia, eosinophilia, thrombocytopenia, leucocytosis, reticulocytosis, lymphadenopathy, agranulocytosis, purpura*)
- tiredness, headache, shortness or breath when exercising, dizziness or pale skin (*pure red cell aplasia, anaemia, aplastic, haemolytic, megaloblastic, folic acid deficiency*)
 - difficulty urinating (*urinary retention*)
 - passing less urine than normal (which may be accompanied by a lack of energy, vomiting, headache and confusion) (*elevated BUN/azotaemia, albuminuria, oliguria, renal failure, water intoxication*)
 - blood in the urine (*haematuria, interstitial nephritis*)
 - persistent nausea or vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and/or eyes, dark coloured urine, light coloured bowel motions, pain in the abdomen (*elevated hepatic enzymes, cholestatic jaundice, parenchymal (hepatocellular, granulomatous or mixed type hepatitis)*)
 - sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing (*anaphylactic reactions, angioedema*)
 - severe skin rash, itching, hives, blisters or peeling skin, which may be accompanied by fever, chills, headache, swollen glands, stomach pain or aching joints and muscles (*allergic skin reactions, severe urticaria, pruritis, bullae, vesicles, Stevens-Johnson Syndrome, erythema multiforme and nodosum, toxic epidermal necrolysis, exfoliative dermatitis, erythroderma, SLE-like syndrome, multi-organ hypersensitivity disorder*)
 - symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal (*photosensitivity*)
 - painful swelling in the arms or legs (*peripheral neuritis*)
 - swelling and redness along a vein which is extremely tender when touched (*thrombophlebitis*)
 - painful lumps under the skin with a fast heart beat, fever and weight loss (*periarteritis nodosa*)
 - fever, difficulty breathing, wheezing, chest congestion, cough and phlegm (*pulmonary hypersensitivity with fever, dyspnoea, pneumonitis, pneumonia, respiratory depression*)
 - signs that blood clots may have formed, such as severe sudden headache, sudden loss of coordination, blurred vision, loss of vision, slurred speech, numbness in an arm or leg, pain in the calves, thighs or chest, shortness of breath, coughing blood (*thromboembolism*)
 - headache, stiff neck, muscle spasms, extreme sensitivity to bright light (*aseptic meningitis with myoclonus and peripheral eosinophilia*)
 - change in heart beat (fast, slow, irregular), sometimes with fainting (*cardiac conduction disturbances, bradycardia, Stokes-Adams attacks and syncope associated with AV block, arrhythmias*)
 - shortness of breath, swelling of the feet and legs, weight increase due to fluid build-up (*congestive heart failure, oedema, fluid retention, weight increase, aggravation of coronary insufficiency*)
 - sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure which may lead to coma (*neuroleptic malignant syndrome*)
 - severe upper stomach pain, often with nausea and vomiting (*pancreatitis*)
 - *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.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people. Some of these side effects (for example, changes in thyroid function, structure of bones, high cholesterol or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

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

You may not experience any of them.¹¹

After using [Medicine name]

This information will be product specific. See general statements in Second Edition of the Usability Guidelines, including:

Storage

Keep your tablets/suppositories/eyedrops/ointment etc. in the pack/bottle until it is time to take them.

If you take the tablets/suppositories/eyedrops/ointment etc. out of the pack/bottle they will not keep well.

Keep your tablets/suppositories/eyedrops/ointment etc. 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 on a window sill or in the car on hot days. 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

¹¹ Consider placing this statement at the beginning of this section.

ground is a good place to store medicines.

Injections only:

Storage

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

Disposal

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

Product description

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

What it looks like

Ingredients

Active ingredients:

- *list actives*

Other ingredients

- *list excipients*

[Medicine name] does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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*

[Medicine name]