

Medicine Name[®] (*phonetic spelling if required*)

Generic name

Consumer Medicine Information

Name
Address
Address

What is in this leaflet¹

Standard information as suggested in Usability Guidelines

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 benefits². Your doctor has weighed the risks of you taking Medicine Name against the benefits they expect it will have for you.

Alternative:

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Medicine Name against the benefits this medicine is expected to 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.

What Medicine Name is used for

¹ Depending on the length of your CMI, consider using a table of contents (see Usability Guidelines)

² Consider reversing "risks" and "benefits".

Medicine Name is used to treat depression. It belongs to a group of medicines called tricyclic/tetracyclic antidepressants/ selective serotonin reuptake inhibitors (SSRIs)/ monoamine oxidase inhibitors (MAOIs)/ reversible monoamine oxidase inhibitors (RIMAs) (*as appropriate*).

Alternative:

Medicine Name is used to treat depression. There are many different types of medicines used to treat depression. Medicine Name belongs to a group of medicines called.. (*as appropriate*).

Depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

Medicine Name corrects this chemical imbalance and may help relieve the symptoms of depression.

Alternative:

Antidepressants are thought to work by their action on brain

chemicals called amines which are involved in controlling mood.

OCD indication:

It is also used to treat obsessive compulsive disorder (OCD)³. The symptoms of OCD vary from patient to patient. Check with your doctor if you need more information.

Bed-wetting indication:

It is also used to treat bed-wetting in children (*age can be specified*) providing there is no physical cause for the problem (eg something wrong with the bladder itself).

Non-approved uses:

Your doctor, however, may prescribe Medicine Name for another purpose. Ask your doctor if you have any questions about why Medicine Name has been prescribed for you.

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

Before you take Medicine Name

³ The location of this statement will depend on the sensible flow of the CMI

When you must not take it

Do not take Medicine Name if:

1. you have an allergy to Medicine Name or any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction to Medicine Name may include... (as listed in PI)

2. you are taking another anti-depressant medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.

Taking Medicine Name with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

3. you are pregnant.

Medicines like Medicine Name may harm the developing baby.

4. you are breast-feeding.

Like many other medicines, Medicine Name can pass into breastmilk and may harm your baby.

Include other contraindications as listed in PI.

Tampering and expiry date warnings:

Do not take Medicine Name if the packaging is torn or shows signs of tampering

Do not take Medicine Name if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work (as well).

If you are not sure whether you should start taking Medicine Name, contact your doctor.

Before you start to take it

You must tell your doctor if:

1. you are allergic to any other medicines, foods, dyes or preservatives

2. you have or have had any other health problems or medical conditions, including:

- (as per PI)

3. you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using Medicine Name when pregnant.

4. you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of using Medicine Name when breastfeeding.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop⁴.

Some commonly used medicines that may interfere with Medicine Name include:

- (as per PI)

Alternatives:

Some medicines may interfere with Medicine Name. These include:

- (as per PI)

These medicines may be affected by Medicine Name or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Medicine Name with other medicines.

Your doctor or pharmacist may have more information on

medicines to avoid while taking Medicine Name.

If use in children a contraindication:

Do not give Medicine Name to a child under x years.

The safety and effectiveness of Medicine Name in children have not been established.

Use in people over 65 years:

If you are 65 years or older, you should be especially careful while taking Medicine Name. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

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

How to take Medicine Name

The following information will be product specific and depend on your PI. These headings and information have been suggested but may not be appropriate in all cases:

Take Medicine Name exactly as your doctor has prescribed.

How much to take

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

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

They/These directions 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

⁴ Alternatively, place under "When you must not use/take it".

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

Swallow Medicine Name with a glass of water.

Alternatives:

If you are taking the dispersible tablets, allow the tablets to dissolve in a glass of water, then drink it straight away.

Swallow Medicine Name whole with a full glass of water. Do not chew them.

The tablets have a special coating to stop them dissolving until they have passed through the stomach into the bowel. Chewing them would destroy the coating.

Switch statement for RIMAs:

It may be possible to change from other antidepressants to Medicine Name by ceasing the other antidepressant one day and starting Medicine Name the next. However, you should follow your doctor's instructions carefully and report any

How long to take it

According to indication:

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so don't be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take Medicine Name for several months or even longer to make sure the benefits will last. Continue taking it until your doctor tells you to stop.

Alternative:

Most antidepressants 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. You may need to take Medicine Name for several months

or longer. Continue taking it until your doctor tells you to stop.

If you forget to take it
(as per Usability Guidelines)

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not double a dose to make up for the dose you have missed.

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

Alternative (for nocte dosing):

If you normally take the tablets only at bedtime and a dose is missed, do not take the missed dose the next morning until you have checked with your doctor.

The medicine may cause some side effects during the day if you take the whole dose in the morning.

Do not take a double dose for the one that you missed.

Alternative:

Do not take an extra dose. Wait until the next day and take your normal dose then. Do not try to make up for the dose you have missed by taking more than one dose at a time.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre⁵ (telephone 13 11 26) for advice, or go to casualty at your nearest hospital² if you think you or anyone else may have taken too much Medicine Name, even if there are no signs of discomfort or poisoning. You may need urgent medical

attention. Keep telephone numbers for these places handy.

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

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

Children - TCAs:

Children are much more sensitive than adults to tricyclic antidepressants. An accidental overdose is especially dangerous.

While you are taking Medicine Name

Things you must do

Tell your doctor immediately⁶ if you become pregnant while taking Medicine Name.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking Medicine Name.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor)

Tell all doctors, dentists and pharmacists who are treating you that you are taking Medicine Name.

Your doctor may ask you to stop taking Medicine Name x days before elective surgery.

Alternative - MAOIs:

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Medicine Name or have used it in the last two weeks. Carry an alert card or wear an SOS bracelet which tells the doctor you are taking Medicine Name.

These are helpful if you are in an accident and cannot talk.

⁵ Consider including the relevant New Zealand telephone numbers here.

⁶ Use "immediately" if pregnancy is a contraindication.

Food, drinks - MAOIs:

Avoid foods that have been aged or fermented. Avoid any food that has caused you unpleasant reactions previously. Food and drinks to be avoided while taking Medicine Name include:

- **matured cheeses; meat, fish, poultry, pate or yoghurt that is not fresh; protein extracts such as Marmite, Vegemite, Bonox, Bovril, Promite; packaged soups or stock cubes; pods of broad beans or sauerkraut; smoked or pickled fish; sour cream; soy bean products eg soy sauce, miso, tofu; avocado; yeast extracts; banana skins; red wines such as chianti; home brewed beers or liqueurs.**

Certain foods and drinks must be avoided during treatment with Medicine Name and for two weeks after ceasing therapy. Medicine Name reacts with a chemical found in a variety of foods. This reaction may cause sudden high blood pressure which may be experienced as severe headache, nausea, vomiting or rapid heart beat.

Alternative:

Talk to your doctor about what foods you should avoid.

Medicine Name reacts with alcohol and certain foods and drinks that contain the chemical tyramine.

The following foods and drinks may react with Medicine Name:

cheese (cooked or plain), yoghurt, flavoured textured vegetable protein, liver, smoked or fermented meat, fish or fish beverages, hung game, broad bean pods, all beer, wine or any other kind of alcohol.

Experience has shown that the above foods should be avoided for two weeks even after you stop taking Medicine Name. If you use any of the foods or drinks that should be avoided, you may have some reactions such as headache, or other symptoms due to a rise in your blood pressure. If you have a

reaction after eating one of these foods, call your doctor.

If you took a small amount of one of these foods one time, without a reaction, it does not mean you will not have a reaction the next time.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets (capsules etc) are not helping your condition.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

This will help your doctor to determine the best treatment for you.

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

Your doctor may want to take some blood tests and check your heart and blood pressure from time to time. This helps prevent unwanted side effects.

Dry mouth - TCAs:

Tell your doctor or dentist if your mouth feels dry and this lasts for more than 2 weeks.

Medicine Name may cause dry mouth. Continuing dryness of the mouth may increase the chance of dental disease, including tooth decay and gum disease. This can be relieved by frequent sips of water, sucking sugarless lollies or chewing sugarless gum.

Things you must not do

Do not stop taking Medicine Name, or lower the dose, without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Suddenly stopping Medicine Name may cause..

- *(list any withdrawal symptoms in PI).*

Do not drive or operate machinery until you know how Medicine Name affects you⁷.

Medicine Name may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

if indicated for enuresis in children:

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.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Do not use Medicine Name to treat any other complaints unless your doctor says to⁸.

Things to be careful of

Be careful driving or operating machinery until you know how Medicine Name affects you⁹.

Medicine Name may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

Make sure you know how you react to Medicine Name before you drive or operate machinery .

*Alcohol:
(TCAs)*

⁷ Alternatively, depending on the PI, a statement could be placed under "Things to be careful of".

⁸ The Usability Guidelines suggest including this statement and the one above under "Before you take/use it", but consider including them here under "While you are using Medicine Name".

⁹ Alternatively, depending on PI, place under "Things you must not do".

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 for depression.

(SSRIs / RIMAs)

Although drinking moderate amounts of alcohol is unlikely to affect your response to Medicine Name, your doctor may suggest avoiding alcohol while you are being treated for depression.

(MAOIs)

Avoid or reduce the amount of alcohol you drink. Do not drink more than two of the allowed standard drinks (spirits, white wine or commercial beers). Alcohol may make you more sleepy, dizzy and lightheaded than usual.

Caffeine (MAOIs):

Avoid large amounts of caffeine-containing foods or drinks such as chocolate, coffee, tea or cola. These may trigger off a migraine-like headache in some people taking Medicine Name.

Switching to MAOIs (except RIMAs)

You should wait at least 14 days after stopping Medicine Name before starting an anti-depressant from the MAOI group.

Older people:

Older people may become confused when taking Medicine Name. Families and carers should be aware of this. Special care may be needed.

Delayed effects (except RIMAs)

After you have stopped taking Medicine Name, you should still be careful for 1 or 2 weeks because some of the medicine will still be in your blood stream.

Alternative (MAOIs):

After you stop taking Medicine Name, you must continue to follow the restrictions regarding food, alcohol and other medications for two weeks.

All of the above precautions are important even after you have stopped taking Medicine Name.

The effects of Medicine Name may last for x days after you have stopped it.

Side effects

Only the opening general statements will be consistent in this section. Other statements will be product specific and consistent with the approved PI.

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 depression, but it may have unwanted side effects in some 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.

Alternative:

Check with your doctor as soon as possible if you have any problems while taking Medicine Name, even if you do not think the problems are connected with this medicine or are not listed in this leaflet.

Like other medicines, Medicine Name can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist any questions you may have.

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

- *List as per PI*

These side effects are usually mild.

or:

These are the more common side effects of Medicine Name.

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

- *List as per PI*

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

If any of the following happen, stop taking Medicine Name and tell your doctor immediately or go to casualty at your nearest hospital:

- *List as per PI*

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

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

or

Some people may get other side effects while taking/using Medicine Name.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Medicine Name

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

Storage

Keep your tablets/capsules in their container until it is time to take them.

If you take the tablets (capsules etc) out of their container they may not keep well.

Keep Medicine Name in a cool, dry place where it stays below 30°C. Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

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

Disposal

If your doctor tells you to stop taking Medicine Name, or the tablets (capsules etc) have passed their expiry date, ask your pharmacist what to do with any tablets (capsules etc) left over.

Product description

This information will be product specific. The Usability guidelines suggest the information should be presented in the following order.

What it looks like

Ingredients

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

Medicine Name does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Medicine Name

Manufacturer/Distributor/Supplier

Include:

- Name and address of sponsor
- ARTG number
- Date of preparation

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 Usability Guidelines wherever possible.