

Dosulepin Mylan

dosulepin (dothiepin) hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dosulepin Mylan.

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 Dosulepin Mylan against the benefits they expect it will have for you.

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

Please read this leaflet carefully and keep it with the medicine.

You may need to read it again.

What Dosulepin Mylan is used for

Dosulepin Mylan is used to treat depression.

Dosulepin Mylan 25 mg capsules can be used at any stage in the treatment of depression. However, the higher strength Dosulepin Mylan 75 mg tablets are approved only for the maintenance treatment of depression (after your symptoms have improved).

Dosulepin Mylan belongs to a group of medicines called tricyclic antidepressants (TCAs). TCA medicines work by correcting the imbalance of certain chemicals in the brain. These chemicals, called amines, are involved in controlling mood. By correcting this imbalance,

TCAs can help relieve the symptoms of depression.

Ask your doctor if you have any questions about why Dosulepin Mylan has been prescribed for you.

Your doctor may have prescribed Dosulepin Mylan for another reason.

Dosulepin Mylan is not approved for use in children and adolescents below 18 years of age for the treatment of depression.

The safe use and effectiveness of Dosulepin Mylan in treating depression, for this age group has not been established.

Dosulepin Mylan is available only with a doctor's prescription.

Before you take Dosulepin Mylan

When you must not take it

Do not take Dosulepin Mylan if you are allergic to:

- any medicine containing dothiepin (such as Prothiaden).
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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
- discolouration of the skin upon exposure to sunlight.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take Dosulepin Mylan if you have epilepsy.

Dosulepin Mylan may increase the chance of fits or convulsions.

Do not take Dosulepin Mylan if you recently had a heart attack, for example within the past two months.

Dosulepin Mylan may cause irregular and/or rapid heartbeat.

Do not take Dosulepin Mylan if you have liver failure.

Your body may not be able to remove Dosulepin Mylan from your system.

Do not take Dosulepin Mylan if you are taking a medicine called a monoamine oxidase inhibitor (MAOI), or have taken a MAOI within the last 14 days.

Stop taking MAOIs at least 14 days before starting Dosulepin Mylan.

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

If you are not sure whether you have been taking a MAOI medicine, ask your doctor or pharmacist.

MAOIs are medicines used to treat depression and symptoms of Parkinson's disease, such as phenelzine (Nardil), tranylcypromine (Parnate), moclobemide (eg. Aurorix Arima) and selegiline (Eldepryl, Selgene).

Do not take this medicine after the expiry date printed on the pack has passed.

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

Do not take Dosulepin Mylan if the packaging is torn or shows signs of tampering or the tablets or capsules do not look quite right.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

There have been reports of some babies experiencing complications immediately after delivery. Your doctor will discuss the possible risks and benefits of taking Dosulepin Mylan during pregnancy.

Tell your doctor if you are breast-feeding or wish to breastfeed.

Like many other medicines, Dosulepin Mylan passes into breast milk.

Your doctor will discuss the risks and benefits of taking Dosulepin Mylan when breastfeeding.

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

- heart or blood vessel problems
- liver problems or hepatitis
- kidney problems or difficulty passing urine (water)
- glaucoma, a condition characterised by an increased pressure in the eye
- prostate problems
- difficulty in passing urine
- thyroid problems

- any other mental illness, such as schizophrenia or manic depression (alternating periods of elation/overactivity and depressed mood)
- family history of suicide or manic depression.

Tell your doctor if you plan to have surgery or if you are undergoing electroshock therapy.

If you have not told your doctor about any of the above, tell him/her before you start taking Dosulepin Mylan.

Taking other medicines

Do not take Dosulepin Mylan if you are taking a monoamine oxidase inhibitor (MAOI) such as:

- phenelzine (Nardil) and tranylcypromine (Parnate), moclobemide (eg. Aurorix, Arima), used to treat depression
- selegiline (Eldepryl, Selgene), used to treat symptoms of Parkinson's disease.

Wait at least 14 days after stopping your MAOI before starting Dosulepin Mylan.

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

Some medicines Dosulepin Mylan may interfere with each other. These include:

- sleeping tablets/sedatives, anti-anxiety medicines
- medicines used to treat epilepsy
- some medicines used to treat high blood pressure or other heart conditions
- some medicines used to relieve stomach cramps
- medicines used to treat Parkinson's disease
- medicines for travel sickness
- some cough and cold preparations

- some medicines for hayfever and allergies
- certain medicines for weight loss
- thyroid hormone medicines.

These medicines may be affected by Dosulepin Mylan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Dosulepin Mylan.

How to take Dosulepin Mylan

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 pack, ask your doctor or pharmacist for help.

How much to take

The dose varies from person to person.

Your doctor will tell you how much Dosulepin Mylan you need to take each day and when to take it. This depends how well you respond to Dosulepin Mylan and whether or not you are taking any other medicines.

The usual starting dose is 25 mg three times daily for one to two weeks. Your doctor may then increase your dose, up to a maximum of 200 mg per day.

Once your symptoms improve, your doctor will then slowly reduce your

dose to the lowest effective dose which maintains relief of symptoms.

Elderly people over 65 years of age and those with liver or kidney problems may need smaller doses.

How to take it

Swallow the tablets or capsules with a full glass of water.

The 75 mg tablets can be divided in half along the breakline if advised by your doctor or pharmacist.

When to take it

Dosulepin Mylan can be taken as a single dose (e.g. at bedtime) or as divided doses (e.g. three times a day). Your doctor will advise you.

Take your medicine at about the same time each day.

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

How long to take it

Continue taking Dosulepin Mylan for as long as your doctor recommends.

The length of treatment will depend on how quickly your symptoms improve.

Most medicines for depression take time to work, so do not be discouraged if you do not 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 the full benefit of Dosulepin Mylan.

Even when you feel well, you will usually have to take Dosulepin Mylan for several months or longer, to make sure that the benefits last.

If you forget to take it

IF YOU TAKE ONE DOSE A DAY (AT BEDTIME)

If you forget to take Dosulepin Mylan before you go to bed and wake up late in the night or early in the morning, do not take the

missed dose until you have checked with your doctor.

You may have difficulty waking up, or experience drowsiness in the morning and during the day.

IF YOU TAKE MORE THAN ONE DOSE A DAY

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, 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.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (for Australia telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Dosulepin Mylan.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Too much Dosulepin Mylan may make you tremble, agitated and/or have difficulty walking. Other signs include fitting or convulsions, unusual muscle movements, difficulty breathing, a very high temperature or irregular heartbeat as well as other serious heart problems.

Keep Dosulepin Mylan out of the reach of children.

Children are much more sensitive than adults to medicines such as Dosulepin Mylan. An accidental overdose is especially dangerous in children

While you are taking Dosulepin Mylan

Things you must do

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide.

These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in young adults under 25 years of age.

Contact your doctor or a mental health professional right away or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Families and caregivers of children and adolescents being treated with Dosulepin Mylan need to monitor these patients for the emergence of:

- anxiety
- agitation
- panic attacks
- insomnia
- irritability
- aggressiveness
- impulsivity
- restlessness or difficulty sitting still

- hypomania
- mania
- unusual changes in behaviour

This will help your doctor determine the best way to control these feelings

Tell your doctor if you feel Dosulepin Mylan is not helping your condition.

Keep all of your doctor's appointments so that your progress can be checked.

If you are taking Dosulepin Mylan for a long time, your doctor may ask you to have your eyes tested regularly.

If you become pregnant while taking this Dosulepin Mylan, tell your doctor immediately. Do not stop taking your tablets or capsules until you have spoken to your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Dosulepin Mylan.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Your doctor may ask you to temporarily stop taking Dosulepin Mylan a few days before elective surgery.

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.

Things you must not do

Do not drive or operate machinery until you know how Dosulepin Mylan affects you.

Dosulepin Mylan may cause drowsiness, dizziness or light-headedness in some people. If any of these occur, do not drive, operate

machinery or do anything else that could be dangerous.

Do not take Dosulepin Mylan to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking Dosulepin Mylan suddenly, your condition may worsen or you may feel sick (nausea), irritable, have a headache, difficulty sleeping or excessive sweating.

Other more serious complications such as fits (convulsions) or blood clots may occur.

If possible, your doctor will tell you how to gradually reduce the amount of Dosulepin Mylan you take each day before stopping the medicine completely.

Things to be careful of

Be careful when drinking alcohol while taking Dosulepin Mylan. Combining Dosulepin Mylan and alcohol can make you more drowsy, dizzy or lightheaded.

Your doctor may suggest you avoid alcohol while being treated for depression

If you feel light-headed, dizzy faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful if you are older than 65 years of age.

Elderly people may become confused when taking Dosulepin Mylan. Families and carers should be aware of this. Special care may be needed.

Tell your doctor or dentist if your mouth continues to feel dry for more than 2 weeks.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dosulepin Mylan.

This medicine helps most people with depression, 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 attention 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 (such as confusion).

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

- dry mouth
- increased sweating
- feeling sick (nausea), vomiting
- constipation
- blurred vision
- drowsiness, dizziness, light-headedness
- tremor
- increased or decreased sex drive

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- fast or irregular heart beat
- ongoing difficulty with passing urine
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- unusual bruising or bleeding
- tingling or numbness of the hands or feet
- severe pain in the stomach with bloating, gut cramps and vomiting
- symptoms of liver disease such as yellowing of the eyes or skin (jaundice) and passing dark coloured urine
- feeling anxious, restless, or confused
- abnormal ideas, hallucinations
- sudden mood swings alternating from one of excitement, overactivity and uninhibited behaviour to a depressed mood
- uncontrollable movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk or stiffness of the arms and legs.

The above list includes serious side effects that may require medical attention.

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

- chest pain
- fainting or collapse
- allergic symptoms such as skin blisters, rash, itching or hives; swelling of the face, mouth, lips, throat or neck; difficulty swallowing or breathing;
- seizures or fits.

The above side effects are not common but very serious. You may need urgent medical attention or even hospitalisation.

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

Other side effects not listed above may also occur in some people.

After taking Dosulepin Mylan

Storage

Keep your Dosulepin Mylan tablets or capsules in the pack until it is time to take them.

If you take the tablets or capsules out of the pack they may not keep well.

Keep your Dosulepin Mylan tablets or capsules in a cool dry place where the temperature stays below 30 °C for tablets and below 25 °C for capsules.

Do not store Dosulepin Mylan or any other medicine in the bathroom or near a sink. Do not leave Dosulepin Mylan on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Dosulepin Mylan 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.

Disposal

If your doctor tells you to stop taking Dosulepin Mylan or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Dosulepin Mylan is available in two strengths:

- Dosulepin Mylan 25 - hard capsule with green and red cap in PVC/PVdC/aluminium blister

packs. Each pack contains 50 capsules.

- Dosulepin Mylan 75 - round, red, scored film-coated tablet marked "DT" over a breakline over "75" on one side and a Greek alpha symbol on the other. Each pack contains 30 tablets.

Ingredients

Dosulepin Mylan 25 capsules

Active ingredient:

dosulepin (dothiepin) hydrochloride 25 mg.

Inactive ingredients:

- lactose monohydrate
- lactose anhydrous
- povidone
- sodium starch glycollate
- purified talc
- magnesium stearate
- sodium lauryl sulfate
- colloidal anhydrous silica
- gelatin
- erythrosine CI 45430 (127)
- iron oxide red CI 77491 (172)
- titanium dioxide (171)
- brilliant blue FCF CI 42090 (133)
- quinoline yellow CI 47005 (104).

Dosulepin Mylan 75 tablets

Active ingredient:

dosulepin (dothiepin) hydrochloride 75 mg.

Inactive ingredients:

- lactose
- maize starch
- povidone
- sodium starch glycollate
- purified talc
- magnesium stearate
- Opadry Red OY-B-25005 (includes colours brilliant scarlet 4R CI 16255 [124], titanium dioxide [171]).

Dosulepin Mylan does not contain gluten, tartrazine or any other azo dyes.

Manufacturer

Dosulepin Mylan is made in
Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

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Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

- Dosulepin Mylan 25 - AUST R
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