

## DOSULEPIN MYLAN

### *Dosulepin (dothiepin) 75mg Tablets*



### What is in this leaflet

This leaflet answers some common questions about DOSULEPIN MYLAN.

It does not contain all the information available on this medicine. 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 using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may want to read it again.

### What DOSULEPIN MYLAN is used for and how it works

Your DOSULEPIN MYLAN tablets contain dosulepin hydrochloride. It belongs to a group of medicines known as tricyclic antidepressants (TCAs).

DOSULEPIN MYLAN is used to treat depression and the anxiety associated with depression. Depression is thought to be caused by a chemical imbalance in parts of the brain. This 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. DOSULEPIN MYLAN works by correcting this chemical imbalance and may help relieve the symptoms of depression.

Your doctor may, however, prescribe DOSULEPIN MYLAN for another reason. Ask your doctor if you have any questions about why DOSULEPIN MYLAN has been prescribed for you.

**DOSULEPIN MYLAN is not recommended for use in children 12 years of age and under. DOSULEPIN MYLAN is not recommended for use in adolescents (13-18 years of age) for the treatment of depression, unless under the supervision of a specialist.**

DOSULEPIN MYLAN is available on prescription from your doctor.

### Before you take DOSULEPIN MYLAN

#### *When you must not take it*

**Do not take DOSULEPIN MYLAN if:**

- you are allergic to dosulepin, other tricyclic antidepressants or any other ingredients listed at the end of this leaflet
- you have liver problems
- you are taking a medicine called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. MAOIs are medicines used to treat depression and symptoms of Parkinson's disease. Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI
- you have recently had a heart attack
- you suffer from epilepsy (fits or convulsions).

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.

#### ***Before you take it***

Tell your doctor if:

- you have had an allergic reaction to any medicine that you have taken previously to treat your current condition
- you have heart or blood vessel problems
- you have liver or kidney problems
- you have difficulty passing urine
- you are having electrical shock treatment
- you are pregnant, plan to become pregnant or are breastfeeding
- you suffer from an overactive thyroid gland (hyperthyroidism) or are receiving thyroid medication
- you suffer from raised pressure in the eye (glaucoma)
- you have suicidal thoughts or have attempted suicide in the past
- you suffer from mania (mood of excitement, over-activity and uninhibited behaviour) or bipolar disorder
- you have a family history of suicide or manic depression
- you have allergies to any other medicines, foods, preservatives or dyes.

**If you are pregnant or plan to become pregnant** you need to discuss with your doctor the risks and benefits of taking dosulepin during pregnancy. The general condition of your newborn baby might be affected by the medicine. If your baby has been exposed to this medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, fits, feeding

difficulties, vomiting, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, constant crying, and sleepiness. If your newborn baby has any of these symptoms, please contact your doctor immediately.

## ***Taking other medicines***

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

Medicines that may interfere with DOSULEPIN MYLAN include:

- **monoamine oxidase inhibitors** (e.g. moclobemide, phenelzine, tranylcypromine used to treat depression and selegiline used to treat the symptoms of Parkinson's disease)
- **other antidepressants** (e.g. SSRIs and tricyclic antidepressants)
- **guanethidine and other adrenergic neurone blocking drugs** (medicines used to treat high blood pressure or other heart conditions)
- **sympathomimetics**, such as nasal decongestants (used for colds or hay fever), weight reducing medicines and **anticholinergic medicines** (used for travel sickness)
- **tranquillisers and central nervous system depressants** (e.g. barbiturates or sleeping tablets or sedatives, anti-anxiety medicines)
- **antihistamines**, medicines for hayfever and allergies
- **anaesthetics**
- **diuretics** (medicines that increase the amount of urine)
- **antiepileptics**, medicines used to treat epilepsy
- **thyroid hormone** medicines.

These medicines may be affected by DOSULEPIN MYLAN or may affect how well DOSULEPIN MYLAN works. You may need different amounts of your medicines

or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DOSULEPIN MYLAN.

---

## **How to take DOSULEPIN MYLAN**

---

### ***How much to take***

Your doctor will tell you how much DOSULEPIN MYLAN you need to take each day. It is important that you take DOSULEPIN MYLAN as directed by your doctor. Do not take more than the recommended dose.

It may take up to 4 weeks before any response to DOSULEPIN MYLAN is noticeable.

The usual dose for an adult is 75 mg of dosulepin daily in divided doses or as a single dose at night. If necessary, your doctor may increase this dose up to 150 mg daily.

If you are elderly, you may be started on a dose of 50 to 75 mg daily.

Your doctor may tell you to take different doses to these. If so, follow their instructions.

The tablets should be swallowed whole with a glass of water.

### ***How long to take it***

For depression, the treatment is usually continued for at least six months to prevent potential recurrence. You may not feel better immediately as most antidepressants take time to work. Do not stop taking DOSULEPIN MYLAN even if you begin to feel better, unless your doctor tells you to do so. Make sure you do not run out of tablets.

### ***If you forget a dose***

If you forget a dose, just take the next dose when it is due. Do not take more than one dose at a time to make up for missed doses.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

---

## **While you are taking DOSULEPIN MYLAN**

---

### ***Things you must do***

Tell all doctors, dentists and pharmacists who are treating you that you are taking DOSULEPIN MYLAN.

Tell your doctor or pharmacist that you are taking DOSULEPIN MYLAN before you start any new medicine.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking DOSULEPIN MYLAN.

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

If you are going to have any blood tests, tell your doctor that you are taking DOSULEPIN MYLAN.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or were not part of your presenting symptoms: anxiety, agitation, panic attacks, insomnia (difficulty sleeping), irritability, hostility (aggressiveness), impulsivity, akathisia (restlessness or difficulty sitting still), hypomania, mania (mood of excitement, over-activity and uninhibited behaviour), worsening of depression.

**Tell your doctor immediately if you have any distressing thoughts (thought of suicide or self-harm) or experiences during this initial period or at any other time.**

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

Do not take DOSULEPIN MYLAN to treat any other complaints unless your doctor tells you to.

Do not stop taking DOSULEPIN MYLAN or lower the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

### ***Things to be careful of***

DOSULEPIN MYLAN may cause drowsiness in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that DOSULEPIN MYLAN does not affect your performance.

Your doctor may suggest avoiding alcohol while you are being treated for depression.

---

## **Side effects**

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

All medicines can have some unwanted 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.

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

- stomach or bowel problems (e.g. nausea, vomiting, constipation)
- drowsiness
- dry mouth or taste change
- increased sweating
- shakiness or tremor
- changes in your sex drive
- dizziness, lightheadedness
- vision problems.

These are the more common side effects of DOSULEPIN MYLAN.

### **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.

These are serious side effects and may require medical attention.

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

- 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.

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

See your doctor if you experience any of the following when you stop DOSULEPIN MYLAN treatment:

- headache
- nausea
- convulsions
- insomnia (difficulty sleeping)
- irritability
- excessive sweating.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

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

---

## **In case of overdose**

You should only take the number of tablets that you have been told.

**Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any DOSULEPIN MYLAN by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.** Take the pack of DOSULEPIN MYLAN with you if you can.

Keep telephone numbers for these places handy.

---

## **Storage conditions**

Do not take this medicine after the expiry date shown on the pack/blister strip or if the packaging shows signs of tampering.

Keep your DOSULEPIN MYLAN tablets in the blister pack until it is time to take them.

Store below 30°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store DOSULEPIN MYLAN, or any other medicine, in the bathroom or near a sink.

## ***Disposal***

If your doctor tells you to stop taking DOSULEPIN MYLAN or if the capsules or tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

---

## Product Description

---

### ***What DOSULEPIN MYLAN tablets look like***

DOSULEPIN MYLAN 75 mg – 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 75 mg tablets

Active ingredient:  
dosulepin hydrochloride 75 mg

Inactive ingredients:

- lactose
- maize starch
- povidone
- purified talc
- sodium starch glycollate
- magnesium stearate
- polyvinyl alcohol
- colourant ponceau 4R lake
- talc
- titanium dioxide
- lecithin soya
- xanthan gum.

---

## If you want to know more

---

Should you have any questions regarding this product, please contact your doctor or pharmacist.

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
P O Box 11183,  
Ellerslie,  
Auckland.

Phone: 0800 579 811

### ***Date of information***

22 March 2021 (based on datasheet dated 22 March 2021).