



**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**Dosulepin
Capsules 25mg and Tablets 75mg**
Dosulepin hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dosulepin is and what it is used for
2. What you need to know before you take Dosulepin Capsules and Tablets
3. How to take Dosulepin Capsules and Tablets
4. Possible side effects
5. How to store Dosulepin Capsules and Tablets
6. Contents of the pack and other information

1. WHAT DOSULEPIN IS AND WHAT IT IS USED FOR

Dosulepin hydrochloride belongs to a group of medicines called antidepressants. Dosulepin Capsules and Tablets are used to treat depression and can also help reduce feelings of anxiety. Your doctor has prescribed dosulepin as other medicines are unsuitable for you. Please ask you doctor or pharmacist if you need more information.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOSULEPIN CAPSULES AND TABLETS

Do not take Dosulepin Capsules and Tablets if:

- You know that you are allergic (hypersensitive) to dosulepin or any of the other ingredients (listed in section 6 of this leaflet)
- You have an irregular heart beat or any other heart problems
- You have liver problems
- You have an eye condition known as glaucoma
- You are a man that has prostate problems (difficulty in passing water or enlarged prostate)
- You have been diagnosed as having mania (feeling over-excited with unusual behaviour)
- You have fits (epilepsy).

Not for use in children.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult.

Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Dosulepin Capsules and Tablets if:
- You are going to the dentist or going to have surgery, tell your surgeon you are taking Dosulepin Capsules and Tablets. It may affect the anaesthetic used
 - You are diabetic, as your blood sugar levels may change whilst taking dosulepin
 - You are receiving electro-shock therapy (ECT) (used in severe depression)

- You have a thyroid (a gland in your neck) problem, difficulty in passing urine, or a tumour of the adrenal gland (a gland above the kidney)
- You suffer from porphyria (a disease causing damage to nerves and skin sensitivity)
- You have a history of mania or psychoses
- You have cardiac disease
- You have severe renal disease
- You have a history of epilepsy
- You suffer from hyperthyroidism.

Other medicines and Dosulepin Capsules and Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular any of the following:

- A medicine used to treat depression called a mono-amine oxidase inhibitor (MAOI). You should not take Dosulepin Capsules and Tablets at the same time as MAOIs or within 14 days of stopping them, e.g. selegiline, rasagiline
- Other medicines used to treat depression called SSRIs (selective serotonin re-uptake inhibitors)
- Any medicines given to you for treating high blood pressure (hypertension) e.g. betanidine, debrisoquine, guanethidine, clonidine
- Medicines used in heart conduction disorders, e.g. quinidine, amiodarone, felcainide, procainamide, propafenone or disopyramide
- Any hayfever/allergy medicines which contains terfenadine or astemizole
- Sotalol, quinidine, Cisapride, pentamidine isetonate, clonidine (medicines for heart or blood pressure problems)
- Halofantrine (a medicine for malaria)
- Rifampicin (an antibacterial)
- Any medicines called barbiturates (eg amylobarbitol for sleeplessness) or methylphenidate (used to treat behavioural problems)
- Any medicine that contains an opioid/narcotic analgesics (these include codeine, morphine, co-proxamol and co-dydramol)
- Tramadol, a strong pain-killer
- Medicines called sympathomimetic agents - these include ephedrine, pseudoephedrine, adrenaline and noradrenaline (these may be found in medicines used to treat heart problems and asthma as well as some decongestants and cough/cold remedies)
- Medicines called antimuscarinics (medicines for Parkinson's Disease, stomach and bladder problems)
- Pimozide and sertindole (medicines for serious mental problems)
- Cimetidine (used to treat stomach ulcers)
- Diuretic medicines ("water tablets")
- Calcium channel blockers (medicine for heart problems eg. amlodipine, diltiazem, nifedipine, verapamil)
- Medicines for epilepsy or fits e.g. phenytoin, primidone, carbamazepine
- Oestrogen-containing contraceptives (these may decrease the antidepressant effect of dosulepin)
- Local anaesthetics
- Quinolone antibiotics e.g. moxifloxacin
- Atomoxetine used to treat Attention-Deficit / Hyperactivity Disorder (ADHD)
- Warfarin, coumarin or other anticoagulants, as there could be changes in bleeding times
- Ritonavir used in the treatment of HIV.

Dosulepin Capsules and Tablets with food, drink and alcohol

Dosulepin can make you feel drowsy. If you drink alcohol with these capsules or tablets this can make you feel more drowsy.

The capsules and tablets should be swallowed whole with a drink of water. Do not chew them.

Pregnancy and breast-feeding

If you are or think you might be pregnant or you plan to become pregnant, or if you are breast-feeding you must tell your doctor before you take this medicine. Your doctor will decide if you can take these capsules or tablets.

Driving and using machines

Dosulepin can make you feel drowsy. Do not drive, operate machinery or do anything that requires you to be alert until you know how the capsules or tablets will affect you.

Feeling drowsy in the day may lessen as treatment continues, but if drowsiness becomes a problem, you should tell your doctor.



FRONT SIDE

Dosulepin Tablets contain Ponceau 4R (E124)

Dosulepin Capsules contain lactose and ponceau 4R (E124) If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Ponceau 4R (E124) may cause allergic reactions.

Information on sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet and capsule, i.e. is essentially 'sodium-free'.

3. HOW TO TAKE DOSULEPIN CAPSULES AND TABLETS

Your doctor will tell you how many capsules or tablets to take and when you should take them. This will also be on the carton label. Ask your pharmacist or doctor for help if you are not sure how to take your capsules or tablets or if you want more information.

The capsules and tablets should be swallowed whole with a drink of water. Do not chew them.

The usual dose is:

Adults: One 25mg capsule three times a day or one 75mg tablet at night. In some cases the doctor may increase your dose, if he considers this necessary. Normally not more than 9 capsules or 3 tablets should be taken each day

Elderly: The usual starting dose is between 1 and 3 capsules or tablets a day.

It may take two to four weeks of treatment before you begin to see an improvement in your mood although you might feel there is an improvement in your anxiety symptoms before then. It is important that you keep taking these capsules or tablets until your doctor tells you to stop.

If you take more Dosulepin Capsules or Tablets than you should

You should only ever take the number of capsules or tablets that your doctor has told you to take. Do not change the dose yourself. If you think your capsules or tablets are not working well enough, speak to your doctor to see if the dose can be increased.

Dosulepin may seriously harm you and may be life threatening if you take too many capsules or tablets. You should SEEK IMMEDIATE HELP if a child takes any capsules or tablets or if you or anybody else accidentally takes too many capsules or tablets. Remember to take the pack with you, even if it is empty. The main symptoms of over dose are unconsciousness, convulsions, reduction in heart and lung function and life threatening heart rhythm disorders which may even occur after apparent recovery. Remember to take the pack with you, even if it's empty.

If you forget to take Dosulepin Capsules or Tablets

Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a forgotten dose. If you are unsure, check again with your doctor or pharmacist.

If you stop taking Dosulepin Capsules or Tablets

Do **not stop** taking dosulepin just because you feel better. If you stop taking dosulepin too soon, your condition may get worse. Withdrawal symptoms may include insomnia, irritability, headache, nausea, giddiness, panic-anxiety, restlessness and increased sweating.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dosulepin Capsules and Tablets can cause side effects, although not everybody gets them.

If you get any of the following rare side effects (that affect less than 1 person in 1000) after taking these capsules or tablets, you should contact your doctor immediately:

- Yellowing of the skin or whites of the eyes (jaundice)
- Hepatitis (damage to the liver causing dark urine, jaundice, nausea and fever)
- A fever (high temperature, sweating, shivering)
- Discomfort around the right lower rib cage
- Changes in the blood including bone marrow (these will be found if you have blood tests)
- Severe mood changes such as extreme excitability
- Fits

The most common side effects (that affect less than 1 person in 10) are:

- Dry mouth
- Blurred vision
- Changes in the heart beat or heart conduction
- Constipation and difficulty in passing water
- Increased appetite
- Weight gain or weight loss

These side effects usually lessen as treatment continues.

Other side effects you may also experience are:

- Drowsiness
- Increased sweating
- Skin rashes, including itchy rashes and hives
- Tremor (shaking)
- Changes in sexual function
- Low blood pressure, which may cause dizziness or fainting
- An allergic reaction (eg skin sensitivity to light, itching, redness)
- Confusion
- Changes in levels of sugar and sodium in the blood (seen in blood tests)
- Enlargement of the testicles
- Swelling of the breasts in men
- Milk production in the breasts not related to pregnancy or breast feeding
- Impairment of movement
- Abnormal body movements
- Delusions (abnormal thoughts)
- Nervousness
- Seizures
- Speech difficulties
- Dizziness
- Raised blood pressure
- Nausea and vomiting
- Weakness
- Tiredness

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOSULEPIN CAPSULES AND TABLETS

Do not store above 25°C. Keep the capsules and tablets in the original container, and in a safe place (preferably a locked cupboard) where children cannot see or reach them. Your medicine could seriously harm them.

Do not take this product after the expiry date shown on the carton.

If your doctor decides to stop the treatment, you must return any left over capsules or tablets to your pharmacist. Only keep the capsules or tablets if your doctor tells you to.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dosulepin Capsules and Tablets contains

The active substance is dosulepin hydrochloride. Each capsule contains 25mg of dosulepin hydrochloride and each tablet contains 75mg of dosulepin hydrochloride

The other ingredients in the capsules are lactose, maize starch and magnesium stearate. The capsule shell contains gelatin and the colours ponceau 4R (E124), titanium dioxide (E171) and yellow iron oxide (E172). The ink on the capsule contains titanium dioxide (E171), shellac and dimethicone.

The other ingredients in the tablets are tricalcium phosphate, maize starch, povidone, magnesium stearate, purified water, polyvinyl alcohol, talc, Ponceau 4R (E124), macrogol 3350, lecithin, Quinolone Yellow Aluminum lake (E104), Titanium dioxide (E171) and Indigo carmine (E132).

What Dosulepin Capsules and Tablets look like and contents of the pack

Dosulepin Capsules are a white powder encapsulated within a Size '3' hard gelatin capsule with a red body and red cap. TH is printed on the cap and '25' printed on the body in white ink.

Dosulepin Tablets are a round red film coated, biconvex tablets with 'PTN75' debossed on one side and plain on other side.

Dosulepin Capsules and Tablets are provided in packs of 14 or 28 capsules and tablets

**Marketing Authorisation Holder and Manufacturer
Strides Pharma UK Limited**

Unit 4, The Metro Centre
Dwight Road Watford WD18 9SS
United Kingdom.

PL 13606/0097 and PL 13606/0098


This leaflet was last revised 08/2023.



P8901

BACK SIDE

ARTWORK DETAIL LABEL

Product	Dosulepin Tablets and Capsules			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	180 x 300mm		Pack	—
New Item Code	1049329	Old Item Code	1047120	
Colour Shades	 BLACK	No. of Colours	1	

Change Control No.	PC-ODF/2023/502 - Record Number: 394743	Artwork Version	9.0	
Design/Style	Front & Back Printing. To be supplied in the unfolded size.			
Substrate	60 GSM Paper			
Special Instructions	Printing clarity to be clear & sharp.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

180 x 300mm