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Package leaflet: Information for the patient
Dosulepin Hydrochloride 75 mg Tablets
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 or pharmacist
- 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.

What is in this leaflet

In this leaflet:

1. What Dosulepin is and what it is used for
2. What you need to know before you take Dosulepin
3. How to take Dosulepin
4. Possible side effects
5. How to store Dosulepin
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. This medicine is used to treat depression in adults and can also help reduce feelings of anxiety. This medicine will only be used when other medicines have been found to be unsuitable. Please ask your doctor or pharmacist if you need more information.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOSULEPIN

Do not take dosulepin tablets and speak to your doctor if:
- you know that you are allergic (hypersensitive) to dosulepin or any of the other ingredients in these tablets (listed in section 6 of this leaflet).
- you have an irregular heart beat (arrhythmia), have had a recent heart attack or suffer from any other heart problems
- you have liver problems
- you have been diagnosed as having mania (feeling over-excited with unusual behaviour)
- 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 fits (epilepsy).

Not for use in children.

Warnings and precautions:
Talk to your doctor or pharmacist before taking Dosulepin if:
- you are diabetic, as your blood sugar levels may change whilst taking dosulepin
- you are undergoing electroconvulsive therapy (used in severe depression)
- 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 suffer from hyperthyroidism
- you are going to have general or dental surgery, tell your surgeon or dentist you are taking these tablets. It may affect the anaesthetic used.
- you have a thyroid problem, difficulty in passing urine, or a tumour of the adrenal gland (a gland above the kidney)

Thoughts of suicide and worsening of your depression or anxiety disorder
If you are depressed and/or have an anxiety disorder 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.

Other medicines and Dosulepin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any obtained without a prescription.

It is particularly important to tell your doctor or pharmacist if you are taking any of the following medicines as these may affect the safe and effective use of Dosulepin:
- A type of medicine used to treat depression called a monoamine oxidase inhibitor (MAOI). You should not take Dosulepin tablets at the same time as MAOIs or within 14 days of stopping them. E.g. selegiline, rasagiline
- Other types of 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, flecainide, procainamide, propafenone or disopyramide.
- Sotalol, quinidine, Cisapride, pentamidine isethionate, clonidine (a medicine for heart or blood pressure problems)
- Halofantrine (a medicine for malaria).
- Rifampicin (an antibacterial)
- Any medicine used to treat epilepsy (convulsions or fits). e.g. phenytoin, primidone, carbamazepine
- Medicines called barbiturates (e.g., amylobarbitone for sleeplessness)
- Methylphenidate (used to treat some 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 which may be found in medicines used to treat heart problems and asthma as well as some decongestants and cough/cold remedies.
- Any hayfever or allergy medicine containing terfenadine or astemizole.
- 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 e.g. Amlodipine, diltiazem, nifedipine, verapamil)
- 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 breastfeeding you must tell your doctor before you take this medicine. Your doctor will decide if you can take these tablets.

Driving and using machines
These tablets can make you feel drowsy. Do not drive, operate machinery or do anything that requires you to be alert until you know how the tablets will affect you. Feeling drowsy in the day can improve with time, but if drowsiness becomes a problem, you should tell your doctor.

If you drink alcohol with these tablets this can make the feeling of drowsiness worse.

Important information about some of the ingredients of Dosulepin tablets
These tablets contain a sugar called sucrose. 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'.

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3. HOW TO TAKE DOSULEPIN

Full dosing range is not possible with Dosulepin 75 mg tablets, other products are available and may be used for 25 or 50 mg dosing.

Your doctor will tell you how many 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 tablets or if you want more information. The following information is given as a guide only:

The tablets should be swallowed whole with a drink of water. Do not chew the tablets as you may get a bitter taste in your mouth and a temporary numbness of your tongue.

Adults:
The usual starting dose is 1 tablet a day. Your doctor may ask you to increase this to 2 or 3 tablets a day. Your doctor will tell you if you should take the tablets as separate doses throughout the day, or a single dose each evening, usually a couple of hours before you go to bed. Normally, not more than 3 tablets should be taken each day.

Elderly: The usual starting dose is 1 tablet 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 tablets until your doctor tells you to stop.

If you stop taking Dosulepin
Do **not stop** taking these tablets just because you feel better. If you stop taking the tablets too soon, your condition may get worse. Withdrawal symptoms may include insomnia, irritability, headache, nausea, giddiness, panic-anxiety, restlessness and increased sweating. If your doctor wants you to stop taking these tablets, your doctor will ask you to stop gradually.

If you forget to take Dosulepin
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 tablet. If you are unsure, check again with your doctor or pharmacist.

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

These tablets may seriously harm you and may be life threatening if you take too many tablets. **You should seek immediate help if a child takes any tablets or if you or anybody else accidentally takes too many 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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 tablets, you should contact your doctor immediately:
- **a fever (high temperature, sweating, shivering)**
- **yellowing of the skin or whites of the eyes (jaundice)**
- **discomfort around the right lower rib cage**
- **hepatitis (damage to the liver causing dark urine, jaundice (yellowing of the skin or whites of the eyes), nausea and fever)**
- **changes in the blood including bone marrow (these will be found if you have blood tests)**
- **severe mood changes such as extreme excitability**
- **fits**

Common side effects (may affect up to 1 in 10 people) are:
- dry mouth
- blurred vision
- changes in the heartbeat or heart conduction
- constipation
- difficulty passing urine (water)
- increased appetite
- weight gain or weight loss

These side effects tend to improve with time.

Other side effects you may also experience are:
- drowsiness
- increased sweating
- skin rashes, including itchy rashes and hives.
- tremor (shaking)
- changes in sexual function
- 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
- low blood pressure, which may cause dizziness or fainting

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

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOSULEPIN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or container after "EXP." The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What dosulepin contains
- The active substance is dosulepin hydrochloride
- The other ingredients are calcium phosphate, maize starch, povidone, and magnesium stearate.
- The coating ingredients are polyvinyl alcohol, triacetin, talc, titanium dioxide, sucrose, microcrystalline cellulose, Hypromellose, sodium saccharin, lake Ponceau 4R, lake sunset yellow, polyethylene glycol.

What dosulepin looks like and contents of the pack
The tablets are red, circular, convex sugar-coated tablets plain on both sides.
The tablets are available in white opaque PVC-Al blister packs of 28 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Rudipharm Limited
Unit 6, Salbrook Road Industrial Estate
Salbrook Road, Redhill, Surrey, RH1 5GJ, UK

Manufacturer:
Rudipharm Limited
Oak House, Reeds Crescent,
Watford, WD24 4QP, UK

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To listen to or request a copy of this leaflet in Braille, large print or audio please call, 01293827819 (UK only)

Please be ready to give the following information:

Product name	Reference number
Dosulepin Hydrochloride 75mg Tablets	**PL 49565/0059**

This leaflet was last revised in August 2026.

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Leaflet Open Size: 110 x 550 mm
Closed Size: 110 x 30 mm
Non-Printing Colours
Die Cut

Dosulepin Hydrochloride 75mg Tablets PIL
Dimensions: 110 x 550 mm (Open size)

Dosulepin Tablets

Font type: Times New Roman

Headings: 10pt (Bold)

Sub-Heading: 9pt (Bold)

Normal Text: 9pt (Regular)



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