

PACKAGE LEAFLET: INFORMATION FOR THE USER

DOSULEPIN TABLETS 75 mg

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. 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
3. How to take Dosulepin
4. Possible side effects
5. How to store Dosulepin
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1. What Dosulepin is and what it is used for

Dosulepin belongs to a group of medicines called antidepressants. Dosulepin is used to treat depression 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 to dosulepin or any of the other ingredients of this medicine (listed in section 6)
- if you have an irregular heart beat or any other heart problems
- if you have liver problems
- if you have an eye condition known as glaucoma
- if you are a man that has prostate problems (difficulty in passing water)
- if you have been diagnosed as having mania (feeling over-excited with unusual behaviour)
- if you have fits (epilepsy).

Dosulepin should not be given to children.

Warnings and precautions

Take special care with Dosulepin :

- if you are going to have general or dental surgery, tell your surgeon you are taking Dosulepin. It may affect the anaesthetic used.

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 (less than 25 years old) 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.

The use of Buprenorphine together with dosulepin can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Dosulepin”).

Other medicines and Dosulepin

Tell your doctor if you are taking or have taken any of the following medicines as they may affect how your Dosulepin tablets work:

- A medicine used to treat depression called a mono-amine oxidase inhibitor (MAOI). You should not take Dosulepin tablets at the same time as MAOIs or within 14 days of stopping them.
- Other medicines used to treat depression called SSRIs (selective serotonin re-uptake inhibitors)
- Any medicines given to you for treating high blood pressure (hypertension)
- Any hay fever/allergy medicines which contains terfenadine or astemizole
- Sotalol (a medicine for heart or blood pressure problems) or halofantrine (a medicine for malaria)
- Any medicines called barbiturates (e.g. phenobarbital for fits, amylobarbitone for sleeplessness) or methylphenidate (used to treat behavioural problems)
- Any medicine that contains an opioid (these include codeine, morphine, co-proxamol and co-dydramol)
- 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)
- Buprenorphine/opioids- These medicines may interact with dosulepin and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 this medicine.

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

This medicine contains 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.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

Dosulepin tablets also contain colours called sunset yellow and Ponceau red in traces which may cause allergic reactions.

Dosulepin tablets contains benzoate salt

This medicine contains traces of benzoate salt in each dosage unit

3. How to take Dosulepin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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.

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 this medicine until your doctor tells you to stop.

The usual dose is:

Adults:

The usual starting dose is 1 tablet a day. Your doctor may ask you to increase this. 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.

If you stop taking Dosulepin

Do **not stop** taking these tablets just because you feel better. If you stop taking this medicine too soon, your condition may get worse. 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. 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.

4. Possible side effects

Like all medicines, Dosulepin tablets can cause side effects, although not everybody gets them.

If you get any of the following symptoms after taking these tablets, you should contact your doctor immediately:

- a fever (high temperature, sweating, shivering)
- 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).

Common: may affect up to 1 in 10 people

- dry mouth
- blurred vision
- changes in the heart beat
- constipation and difficulty in passing water.

These side effect tend to improve with time.

Other side effects you may also experience are:

- drowsiness
- increased sweating
- skin rashes
- tremor (shaking)
- changes in sexual function
- low blood pressure, which may cause dizziness or fainting.

Rare: may affect up to 1 in 1,000 people

- changes in the blood and changes in hormone levels (these will be found if you have blood tests)
- severe mood changes such as extreme excitability
- fits.

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 or pharmacist. 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 these tablets in the original container.

Keep this medicine out of the sight and reach of children. Your medicine could seriously harm them.

Do not take this product after the 'use by' date shown on the carton.

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

Do not throw away any medicine 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. Content of the pack and other information

What Dosulepin contains

- The active substance is dosulepin hydrochloride.
- The other ingredients in the tablets are calcium phosphate, maize starch, povidone, sodium carboxymethylcellulose, magnesium stearate (E572), hydrolysed gelatin, sucrose and talc (E553). The coating of the tablets also contains small amounts of sucrose, shellac, carnauba wax, beeswax, sodium benzoate, titanium dioxide (E171), ponceau red (E124), sunset yellow (E110) and indigotine (E132). The printing ink contains shellac, black iron oxide (E172) and propylene glycol (E1520).

What Dosulepin looks like and contents of the pack

Dosulepin tablets are red coded with 'APS' or plain on one side and '75/1129' on the reverse.
Dosulepin Tablets are available in pack sizes of 14 and 28.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised: March 2021

PL 00289/0108