



Package leaflet: Information for the user

Doxepin 25 mg and 50 mg capsules

doxepin 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. See section 4.

What is in this leaflet

1. What Doxepin is and what it is used for
2. What you need to know before you take Doxepin
3. How to take Doxepin
4. Possible side effects
5. How to store Doxepin
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1. What Doxepin is and what it is used for

The active ingredient of Doxepin is doxepin hydrochloride. Doxepin is an antidepressant used in adults. It is one of a group of medicines called tricyclic antidepressants. Your doctor has decided that this medicine is suitable for treating your depression.

Depression is a clinical illness. If you have been feeling sad, tearful or unable to enjoy life as you used to, Doxepin may help you to feel better. It may also help if you have difficulty sleeping because of your depression. If you are not sure why you are on these capsules, ask your doctor.

2. What you need to know before you take Doxepin

Do not take Doxepin Capsules:

- if you are allergic to doxepin, tricyclic antidepressants, or any of the other ingredients of this medicine (listed in section 6);
- if you have serious liver problems;
- if you have glaucoma (increased eye pressure);
- if you suffer from difficulty in passing urine;
- if you are breast-feeding;
- if you are taking, or have taken in the last two weeks, any medicines called monoamine oxidase inhibitors (MAOIs for short);
- if you suffer from a type of mood disorder called mania, where you experience an abnormally elevated mood state;
- if the patient is under 18 years of age.

If you suffer from any of the above, speak to your doctor or pharmacist before taking Doxepin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Doxepin:

- if you are pregnant or trying to become pregnant
- if you have any heart problems
- if you have had a heart attack recently
- if you have kidney problems
- if you suffer from epilepsy (fits)
- if you have suicidal thoughts or have attempted suicide in the past

Children

Do not give this medicine to children below 18 years of age. The safety and efficacy in children under 18 years have not been established.

Other medicines and Doxepin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are going to have a surgical operation or dental surgery tell the doctor or dentist in charge that you are taking this medicine.

Some medicines can interfere with the action of Doxepin, and Doxepin can sometimes affect the action of other medicines. Check with your doctor if you are taking any of the medicines listed below:

- Monoamine oxidase inhibitors: these must not be used with Doxepin (see 'What you need to know before you take Doxepin' section above).
- Other antidepressants, barbiturates (used to treat insomnia) or other sleeping medicines or medicines for anxiety: Doxepin will add to their effects and may cause you to feel sleepy or drowsy.
- Medicines to lower blood pressure.
- Sympathomimetics, such as nasal decongestants (used for colds or hay fever) and bronchodilators (used to treat asthma).
- Cimetidine (used to treat ulcers and other stomach complaints).
- Thyroid hormones (used to treat thyroid disorders).
- Chlorpromazine (used to treat mental illness).
- Sublingual nitrates (used to treat angina and heart failure).

Doxepin with alcohol

Be careful when drinking alcohol. Alcoholic drinks (wine, beer, spirits) may affect you much more than usual.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine if you are pregnant, trying to become pregnant or if you are breast-feeding without consulting your doctor.

Driving and using machines

You may feel sleepy when you take these capsules. Do not drive or work with machinery until this effect has worn off.

Doxepin capsules contains lactose and sodium

Doxepin capsules contain lactose which is a type of sugar. 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 capsule, that is to say essentially 'sodium-free'.

3. How to take Doxepin

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The label on the pack will tell you what dose you should take and how often each day to take it.

The recommended dose:

- The usual starting dose is 75 mg daily. This dose may be increased if necessary.
- The maximum recommended dose is 100 mg three times daily.
- The capsules may be prescribed once, twice or three times daily.
- Up to 100 mg can be given as a single dose.

Use in elderly patients and/or patients with liver problems

- If you are elderly these doses may be reduced.
- If you are elderly and require an increased dose of the medicine your doctor may wish to see you regularly.
- If you suffer from liver problems you may also be started on a low dose.

Method of administration:

- Take this medicine only by mouth.
- Swallow the capsules whole with a drink of water.
- Take the capsules while standing or when sitting upright.
- Do not crush or chew the capsules.
- Keep taking the capsules every day

If you take more Doxepin Capsules than you should

Taking too many capsules at once can be dangerous.

Signs and symptoms of mild overdose include drowsiness, stupor, blurred vision and excessive dryness of the mouth. Severe overdose may cause loss of consciousness, reduced breathing rate, convulsions, low blood pressure, unusually fast heart beat or palpitations. If you take too many capsules immediately contact your doctor or nearest hospital Accident and Emergency Department. Do not attempt to drive or work with machinery.

If you forget to take Doxepin Capsules

Do not worry. Take your usual dose at the next correct time. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Doxepin Capsules

You should always check with your doctor before you stop treatment. Your doctor may want you to reduce gradually the amount you are taking before stopping the medicine completely. This may help to prevent a recurrence of the original trouble and reduce the chance of withdrawal effects such as insomnia, irritability and excessive sweating.

How quickly will the treatment start to work

- You may take Doxepin for 2–3 weeks before you start to feel better.
- You must keep taking Doxepin to help you get better.
- See your doctor before your capsules run out.
- Even if you begin to feel better, keep taking your capsules. You may need to keep taking them to stay well.

If you do not feel better

Tell your doctor if you have taken all your medicine and you still feel unwell or if you feel worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

500 mm

250 mm

200 mm

Bone fractures:

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

Doxepin is well tolerated. Most undesirable effects are usually mild and tend to wear off after continued treatment. However, if the side effects are troublesome, your doctor may decide to reduce your dose.

Possible side effects:**Very common (may affect more than 1 in 10 people)**

- drowsiness
- dry mouth
- constipation

These are usually mild. If they last for more than several days, check with your doctor.

Uncommon (may affect up to 1 in 100 people)

If they don't wear off after a few days or trouble you, check with your doctor.

- dizziness, (if you experience dizziness you should be particularly careful to stand up slowly)
- sweating
- blurred vision
- headache
- insomnia
- difficulty in passing urine
- tiredness
- weakness
- weight gain
- upset stomach
- loss of appetite
- vomiting or diarrhoea
- mouth ulcers
- unpleasant taste
- fast heart beat (palpitations)
- changes in sex drive
- swelling of testicles
- chills
- flushing
- hair loss from the scalp
- shakiness or trembling
- numbness in the hands or feet
- feeling of pins and needles
- agitation or confusion
- ringing or buzzing in the ears

Rare (may affect up to 1 in 1,000 people)

The undesirable effects below are rare but they have occurred in patients taking one of the tricyclic antidepressants; however, not all have occurred with Doxepin. You should check with your doctor immediately if any of the following occur:

- skin rash, itching, face swelling; your skin may be more sensitive to sunlight than it is normally
- at high doses particularly in the elderly, unwanted effects on muscles which may cause slowed movements or stiffness of arms and legs, slurred speech or odd tongue or eye movements
- staggering walk which may occur on a mixture of centrally acting medicines
- worsening of an existing mental disorder
- breast enlargement in both men and women, breast milk production when not pregnant or breast feeding
- worsening of asthma
- convulsions (fits) are unlikely unless you already suffer from these
- nightmares, hallucinations (seeing or hearing things that are not there)
- jaundice (yellow eyes or skin)
- changes to the heart rhythm may occur very rarely
- blood disorders; these may cause fever or chills and painful ulceration in the mouth or rectum, or unusual bruising or bleeding
- abnormal blood tests results i.e. change in blood sugar levels, lower sodium content of blood and low blood cell count

Additional side effects in elderly patients

If you are elderly, you may be more likely to be troubled by agitation or confusion.

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 Yellow Card Scheme: 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 Doxepin

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 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 other information**What Doxepin contains**

- The active substance is doxepin (as hydrochloride). Each capsule contains 25 mg or 50 mg doxepin.

The other ingredients are:

Capsule content: lactose monohydrate, maize starch, starch pregelatinized, sodium laurilsulfate, magnesium stearate.

Capsule shell: gelatin, sodium laurilsulfate, titanium dioxide (E 171), iron oxide yellow (E 172).

Printing ink: shellac (E 904), black iron oxide (E 172).

The capsules are free of gluten and sucrose.

What Doxepin looks like and contents of the pack

Doxepin 25mg capsules: Size "3" hard gelatin capsule filled with white to off-white granular powder. Yellow opaque cap and "DOXEPIN 25 MG" printed on white opaque body with black ink.

Doxepin 50mg capsules: Size "2" hard gelatin capsule filled with white to off-white granular powder. Yellow opaque cap and "DOXEPIN 50 MG" printed on yellow opaque body with black ink.

Aluminium/Aluminium blister pack of 10, 20, 28 and 30 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

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Other Formats

To obtain a copy of this leaflet in braille, larger sized text or audio format, please email UKMedInfo@zentiva.com

