

Package leaflet: information for the user

Doxepin 25mg and 50mg hard 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 hard capsules are and what they are used for
2. What you need to know before you take Doxepin hard capsules
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1. WHAT DOXEPIN HARD CAPSULES ARE AND WHAT THEY ARE USED FOR

Doxepin 25mg hard capsules and Doxepin 50mg hard capsules (called Doxepin capsules in this leaflet) contain the active substance Doxepin as doxepin hydrochloride. This belongs to a group of medicines called tricyclic antidepressants. Doxepin is used to treat depression in adults and it may help if you have trouble sleeping because of your depression.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DOXEPIN HARD CAPSULES

Do not take Doxepin hard capsules if you:

- are allergic to doxepin hydrochloride or other tricyclic antidepressant or any of the other ingredients of this medicine (listed in Section 6)
- have a serious liver problem
- have glaucoma (increased eye pressure)
- are breastfeeding
- have difficulty passing urine
- have a disorder called mania where your mood can be artificially high.

Talk to your doctor before taking this medicine if you:

- have a history of suicidal thoughts or have attempted suicide

- are elderly
- have a heart condition
- have problems with your liver or kidneys
- have epilepsy (fits)

Children

Not to be given to children under 18 years.

Other medicines and Doxepin hard capsules

Tell your doctor or pharmacist if you are taking any of the following medicines:

- **Other antidepressants, barbiturates** (for lack of sleep), or other sleeping medicines or medicines for anxiety. Doxepin will increase their effect.
- **Monoamine Oxidase Inhibitors (MAOIs)**. Use of these medicines must stop two weeks before taking Doxepin hard capsules.
- **Cimetidine** used to treat ulcers.
- **Thyroid hormones**
- **Nitrates** to treat angina and heart failure
- **Ephedrine, isoprenaline, noradrenaline** normally given in a hospital setting.
- **Phenylephrine or phenylpropanolamine** for colds or hayfever

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

If you need surgery tell your doctor you are taking Doxepin hard capsules.

Pregnancy and breastfeeding

Tell your doctor before taking this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Breastfeeding

Doxepin can pass into breast milk. Do not breastfeed while taking Doxepin hard capsules.

Fertility

It is not known if doxepin affects fertility.

Doxepin hard capsules and alcohol

Avoid drinking alcohol while taking Doxepin hard capsules. Alcohol may affect you more than usual.

Driving and using machines

Doxepin hard capsules may make you feel drowsy. Do not drive or use machinery if you feel sleepy, wait until the effect has worn off.

Important information about some of the ingredients of Doxepin hard capsules

- This medicine contains:
- **Sodium:** contains less than 23mg of sodium (main component of cooking/table salt) in each tablet, essentially sodium free.
 - **Lactose:** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE DOXEPIN HARD CAPSULES

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

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not or you are not sure, ask your doctor or pharmacist.

Swallow your capsules whole.

Adults

The dose will be decided by your doctor. It can vary between 25mg to 300mg per day. A usual starting dose is 75mg per day.

Elderly or if you have liver or kidney problems

The dose will be decided by your doctor. The starting dose is normally at the low end of the dose range given for adults.

While you are taking this medicine, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you. You may not feel the effect of Doxepin hard capsules for two to three weeks.

Use in children and adolescents

No data are available. Doxepin hard capsules should not be used in children and adolescents aged less than 18 years.

If you take more Doxepin hard capsules than you should

- If you take more than the label states, or if you think a child has accidentally swallowed any capsules, contact the nearest hospital casualty department or doctor **immediately**.
- Take this leaflet with you

If you forget to take Doxepin hard capsules

If you forget a dose, take the next dose as soon as you remember.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Doxepin hard capsules

It is very important that you **do not stop taking** Doxepin hard capsules, even if you feel better or are suffering from a side effect, unless your doctor tells you to. Your doctor will tell you how to stop taking Doxepin hard capsules.

If you stop taking your medicine suddenly, you may suffer from some of the following side effects: unable to sleep, irritability, and sweating.

If you have any further questions on the use of this product, 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.

Bone fractures: An increased risk has been seen in patients taking this type of medicine.

Most undesirable effects are usually mild and tend to wear off after continued treatment. However, if the side effects concern you, your doctor may decide to reduce your dose.

The **most common side effects** are:

- Drowsiness
- Dry mouth
- Constipation

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

Less common or rare side effects are listed below. If they don't wear off after a few days or you are worried, 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 side effects:

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 drugs.
- 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; unusual bruising or bleeding.
- Abnormal blood test results i.e. change in blood sugar levels, lower sodium content of blood and low blood cell count.

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, 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 DOXEPIN HARD CAPSULES

Store below 30°C.

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.

Do not dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Doxepin hard capsules contain

- Doxepin 25mg hard capsule contains 25mg of the active substance, doxepin, as doxepin hydrochloride. The other ingredients are: maize starch, lactose monohydrate, sodium lauryl sulphate (E487) and magnesium stearate. The capsule shell contains indigotine – FD&C blue 2 (E132), titanium dioxide (E171) and gelatin.

- Doxepin 50mg hard capsule contains 50mg of the active substance, doxepin, as doxepin hydrochloride. The other ingredients are: maize starch, lactose monohydrate, sodium lauryl sulphate (E487) and magnesium stearate. The capsule shell contains indigotine – FD&C blue 2 (E132), titanium dioxide (E171) and gelatin.

What Doxepin hard capsules look like and contents of the pack

The Doxepin 25mg hard capsules are white and light blue.

The Doxepin 50mg hard capsules are light blue.

They are supplied in packs of 28 capsules.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in November 2020

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