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

The name of this medicine is Doxepin 25 mg and 50 mg Capsules. The active ingredient is doxepin hydrochloride. Doxepin is an antidepressant. It is one of a group 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 Capsules

Do not take Doxepin Capsules if
- You have ever had an allergic reaction to tricyclic antidepressants, doxepin, or any of the other ingredients of Doxepin Capsules
- You have serious liver problems
- You have glaucoma (increased eye pressure)
- You suffer from difficulty in passing urine
- You are breast-feeding
- You are taking, or have taken in the last two weeks, any medicines called monoamine oxidase inhibitors (MAOIs for short)
- You suffer from a type of mood disorder called mania, where you experience an abnormally elevated mood state

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

Warning and precautions
Talk to your doctor or pharmacist before taking Doxepin Capsules if you
- are pregnant or trying to become pregnant
- have any heart problems
- have had a heart attack recently
- have kidney problems
- suffer from epilepsy (fits)
- have suicidal thoughts or have attempted suicide in the past

The use of Buprenorphine together with Doxepin can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Doxepin Capsules").

Children and adolescents
Doxepin is not for use in children and adolescents who are under 18 years. It is not known if it is safe and effective in these patients.

Other medicines and Doxepin Capsules
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 Capsules (see 'What you need to know before you take Doxepin Capsules' section above).
- **Other antidepressants, barbiturates (used to treat insomnia) or other sleeping medicines or medicines for anxiety.** Doxepin Capsules 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).
- **Buprenorphine / opioids** (used to treat opioid overdose) This medicine may interact with Doxepin 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.

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

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

3. How to take Doxepin Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. You should check with them if you are not sure.
- Your medicine should only be taken by mouth.
- Swallow your 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.
- 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.
- 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.
- The capsules may be prescribed once, twice or three times daily.
- Up to 100 mg can be given as a single dose.

If you take more Doxepin Capsules than you should
Too many capsules at once can be dangerous. Signs and symptoms of mild overdosage include drowsiness, stupor, blurred vision and excessive dryness of the mouth. Severe overdosage 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 dose.

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.

What if you do not feel better?
Tell your doctor if:
- You have taken all your medicine and you still feel unwell

or
- You feel worse.

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 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.

Other side effects that you may experience while taking this medicine are:

Common (may affect up to 1 in 10 people)
- Drowsiness
- Dry mouth
- Constipation

Uncommon (may affect up to 1 in 100 people)
- A skin condition with itching, redness and a burning feeling called skin rash
- Itching
- Face swelling
- Pinky, itchy swellings on the skin, also called hives or nettle rash
- Increased sensitivity of the skin to sun

Rare (may affect up to 1 in 1000 people)
- Difficulty in passing urine
- Breast enlargement in both men and women, breast milk production when not pregnant or breast feeding.
- Changes to the heart rhythm
- Jaundice (yellow eyes or skin)
- Convulsions (fits)
- Seeing, feeling or hearing things that are not there
- Shakiness
- Blood disorders: these may cause fever or chills and painful ulceration in the mouth or rectum
- Ringing or buzzing in the ears
- Excessive secretion of antidiuretic hormone (ADH)

Not Known (frequency cannot be estimated from the available data)
- Insomnia
- Nightmares
- Mouth ulcers
- Stiffness of arms or legs, slurred speech, odd tongue, eye movements
- Nausea
- Vomiting
- Indigestion
- Diarrhoea
- Loss of appetite
- Blurred vision
- Worsening of asthma
- Fast heartbeat
- Chills
- Tiredness
- Excessive sweating
- Flushing
- Excessive weakness
- Suicidal thoughts and behaviour
- High fever
- Hair loss from the scalp
- Dizziness on standing up, especially when getting up from a sitting or lying position.
- Bone fracture
- Changes in sex drive
- Swelling of testicles
- Dizziness
- Headache
- Unpleasant taste
- Weight gain
- Abnormal blood tests results i.e.- change in blood sugar levels, lower sodium content of blood and low blood cell count
- Agitation
- Confusion
- Disorientation
- Trembling
- Numbness in the hands or feet
- Feeling of pins and needles

Reporting of side effects
If you get any side effects, talk to your doctor, nurse 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 the side effects you can help provide more information on the safety of this medicine.

5. How to store Doxepin Capsules

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

Store below 25°C.
Do not use this medicine after the expiry date which is stated on the carton and blister as [EXP.: XX/YYYY]. The expiry date refers to the last day of that month.
Medicines should not be disposed of 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 Capsules contain:

Doxepin 25 mg Capsule. Each capsule contains 25 mg doxepin.
Other ingredients: mannitol, pregelatinised starch, sodium laurilsulfate, magnesium stearate; capsule shell constituents: gelatin, erythrosine (E127), indigotine (E132), titanium dioxide (E171), white ink (shellac, propylene glycol (E1520), titanium dioxide (E171)).

Doxepin 50 mg Capsule. Each capsule contains 50 mg doxepin. Other ingredients: mannitol, pregelatinised starch, sodium laurilsulfate, magnesium stearate; capsule shell constituents: gelatin, erythrosine (E127), indigotine (E132), titanium dioxide (E171), white ink (shellac, propylene glycol (E1520), titanium dioxide (E171)).

What Doxepin Capsules look like and the contents of the pack:
- Doxepin 25 mg Capsules - Blue cap and red body, size 3 hard gelatin capsules, imprinted with 'DP25' on the body in white.
- Doxepin 50 mg Capsules - Blue cap and blue body, size 2 hard gelatin capsules, imprinted with 'DP50' on the body in white.

Doxepin Capsules are available in boxes of 28 capsules.

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