



**Package leaflet:
Information for the user**

**Doxepin 25mg and
50mg Capsules, Hard**

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
6. Contents of the pack and other information

1. WHAT DOXEPIN IS AND WHAT IT IS USED FOR

The name of this medicine is Doxepin 25mg and 50mg Capsules, Hard. The active ingredient is doxepin (as 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

Do not take Doxepin Capsules if:

- You have ever had an allergic reaction to tricyclic antidepressants, doxepin, or any of the other ingredients of this medicine (listed in section 6).
- 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.
- 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 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”).

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 (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 Capsules 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.

Doxepin contains sodium.

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

Doxepin capsule shell contains Azocolouring agents.

May cause allergic reactions.

3. HOW TO TAKE DOXEPIN

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

The recommended dose:

The label on the pack will tell you what dose YOU should take and how often each day to take it. If you are still not sure, ask your doctor or pharmacist.

- 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 75mg daily. This dose may be increased if necessary
- The maximum recommended dose is 100mg 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 100mg 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 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.

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 medicine, ask your doctor, or pharmacist or nurse.

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)

- 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)
- Seizures (convulsions or fits)
- Hallucinations (Seeing, feeling or hearing things that are not there)
- Ataxia (problems with co-ordination, balance and speech)
- Blood disorders: these may cause fever or chills and painful ulceration in the mouth or rectum; unusual bruising or bleeding; anaemia (low red blood cells)
- Ringing or buzzing in the ears
- Urinating less than normal (excessive production of antidiuretic hormone)

Not Known (frequency cannot be estimated from the available data)

- Insomnia (unable to sleep)
- 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via national reporting system listed in 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

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 medicine should be stored in below 30°C.

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 to 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 50mg of doxepin (as hydrochloride)

The other ingredients are Cellulose microcrystalline (grade-102); Starch, pregelatinised (maize starch); Silica colloidal anhydrous; Sodium lauryl sulfate and Magnesium stearate. The capsule shell contains Quinoline yellow (E104), Titanium dioxide (E171), and Gelatin. The capsules are coloured with black printing ink contains Shellac (E904), Black iron oxide (E172) and Potassium hydroxide (E525).

What Doxepin looks like and contents of the pack

The Doxepin 25mg Capsules, Hard are yellow opaque coloured cap and white opaque coloured body size “3” hard gelatin capsules imprinted with 'DOPH' on cap and “25” on body with black ink, filled with white to off-white granules.

The Doxepin 50mg Capsules, Hard are yellow opaque coloured cap and yellow opaque coloured body size “2” hard gelatin capsules imprinted with 'DOPH' on cap and “50” on body with black ink, filled with white to off-white granules.

Blister pack of opaque PVC/PVdC – aluminium foil blisters containing 28 capsules.

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