

# Doxepin

10 mg, 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 Capsules are and what they are 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
6. Contents of the pack and other information

### 1. What Doxepin Capsules are and what they are used for

The name of this medicine is Doxepin 10 mg, 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 Capsules 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 are allergic to tricyclic antidepressants, doxepin, 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 Capsules.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Doxepin Capsules if:

- You are pregnant or trying to become pregnant.
- You have any heart problems.
- You have had a heart attack recently.
- You have kidney problems.
- You suffer from epilepsy (fits).
- You 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 section 2 'Other medicines and Doxepin Capsules').

If you are not sure if any of above applies to you, talk to your doctor or pharmacist before taking this medicine.

#### 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 Capsules, and Doxepin Capsules 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 section 2 'Do not take Doxepin Capsules' 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 Capsules 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.

#### 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 Doxepin Capsules exactly as your doctor has told you. The label on the pack will tell you what dose YOU should take and how often

each day to take it. You should check with your doctor or pharmacist 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.
- For most patients, the recommended 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 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 Capsules for 2-3 weeks before you start to feel better.
- You must keep taking Doxepin Capsules 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.

### 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 Capsules are 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 test 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. 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](http://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 Capsules**

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 and blister foil after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°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 Capsules contain**

Each capsule contains either 10 mg, 25 mg or 50 mg of doxepin as the active ingredient.

The other excipients in each capsule are silica, colloidal anhydrous, magnesium stearate and co-processed starch.

The capsule shell contains:

Doxepin 10 mg Capsules: Gelatin, iron oxide red (E172) and titanium dioxide (E171).

Doxepin 25 mg Capsules: Gelatin, FD & C blue 2 (E132), iron oxide red (E172) and titanium dioxide (E171).

Doxepin 50 mg Capsules: Gelatin, FD & C blue 2 (E132) and titanium dioxide (E171).

Printing Ink - White on each capsule contains shellac (E904), titanium dioxide (E171) and propylene glycol (E1520).

##### **What Doxepin Capsules look like and contents of the pack**

Doxepin 10mg Capsules are red opaque cap and body size '4' hard gelatin capsule, printed with white ink 'Doxepin' on cap and '10 mg' on body.

Doxepin 25mg Capsules are blue opaque cap and red opaque body size '3' hard gelatin capsule, printed with white ink 'Doxepin' on cap and '25 mg' on body.

Doxepin 50mg Capsules are blue opaque cap and body size '2' hard gelatin capsule, printed with white ink 'Doxepin' on cap and '50 mg' on body.

The capsules are packaged in PVC/PVDC-aluminium blister in packs of 28.

##### **Marketing Authorisation Holder**

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