



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 25 mg capsules.

The active ingredient in this medicine is doxepin, a tricyclic antidepressant.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Doxepin capsules:

- if you have suicidal thoughts or have attempted suicide in the past
- 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)

The use of **Buprenorphine** together with Doxepin Capsules can lead to serotonin syndrome, a potentially life-threatening condition (see “If you are taking other medicines”).

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.

Other medicines and Doxepin Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important as some medicines may affect the way Doxepin capsules work.

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.

Tell your doctor, especially, if you are taking any of the medicines listed below:

- **Monoamine oxidase inhibitors** (antidepressant medicines). These medicines must not be used with Doxepin capsules (see ‘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 contraction 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 while taking Doxepin capsules with alcohol as it may cause drowsiness. 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 capsules contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Doxepin capsules

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 capsules should be swallowed whole. Do not crush or chew the capsules.

The usual starting dose is 75 mg daily. This dose may be increased if necessary. The maximum recommended dose is 100 mg taken three times per day.

Use in children and adolescents

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

Use in elderly

It may be necessary to reduce the dose in elderly patients. Follow your doctor's instructions. If you are elderly and require an increased dose of the medicine your doctor may wish to see you regularly.

Use in patients with liver and/or kidney problems

It may be necessary to reduce the dose or start the treatment on a lower dose. Follow your doctor's instructions.

Method of administration

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

Duration of the treatment

- 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.
- Even if you begin to feel better, keep taking your capsules. You may need to keep taking them to stay well.
- See your doctor before your capsules run out.

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.

If you forget to take Doxepin capsules

If you forget to take this medicine, 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 dose 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.

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 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.

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 1,000 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
- flushing, excessive sweating, high fever
- excessive weakness
- suicidal thoughts and behaviours
- hair loss
- dizziness when standing up, especially when from sitting or lying position
- bone fracture
- change in sex drive
- swelling of testicles
- 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.

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 the Yellow Card Scheme, Website: 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 after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from light.

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 capsules contain

- The active substance is doxepin. Each capsule contains doxepin hydrochloride equivalent to 25 mg doxepin.
- The other ingredients are:

Contents of the hard capsule: lactose anhydrous, magnesium stearate (E572), pre-gelatinized starch, sodium laurilsulfate (E487), silica, colloidal anhydrous;

Contents of the hard capsule shell: gelatin, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E 172), brilliant blue FCF – FD&C blue (E 133).

The capsules are free of gluten and sucrose.

What Doxepin capsules look like and the contents of the pack

Doxepin 25 mg capsules are blue and white coloured capsules.

Doxepin 25 mg capsules are available in packs of 28 capsules - PVC/PVdC/aluminium blister strips; 2 rows of 7 capsules per strip, 2 strips in a carton box.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
RPH Pharmaceuticals AB
Box 603
101 32 Stockholm
Sweden

Manufacturer

Recipharm Uppsala AB
Björkgatan 30
SE-751 82 Uppsala
Sweden

The Leaflet was last revised in 08/2021

For information in large print, Braille or on CD, telephone 0800 198 5000.