

Doxepin 25 mg - 50 mg capsules  
190x480 mm  
Myriad Pro regular/bold  
c. 8,8 / 10 condens.

FORMATO PROSPETTI PREPIEGATI  
DIMENSIONI: 190 x 240 mm x 2 = (190 x 480 mm)

**Package leaflet: Information for the patient**

**Doxepin 25 mg capsules**  
**Doxepin 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**

Doxepin capsules are an antidepressant. They contain the active substance doxepin hydrochloride which belongs to 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 doxepin or any of the other ingredients of this medicine (listed in section 6)
- if you have ever been allergic to tricyclic antidepressants
- if you have glaucoma (increased eye pressure)
- if you have serious liver problems
- if you suffer from difficulty in passing urine
- if you are breast-feeding
- 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 are taking, or have taken in the last two weeks any medicines called monoamine oxidase inhibitors (MAOIs for short).

Please tell your doctor or pharmacist if any of the above apply to you, and do not take Doxepin capsules.

**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 seizures/fits (epilepsy)
- have suicidal thoughts or have attempted suicide in the past

**Other medicines and Doxepin capsules**  
**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines**

- Monoamine oxidase inhibitors. These must not be used with Doxepin capsules (see "Do not 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. ↳ senso di alimentazione ↓
- 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)
- Chlorpromazine (used to treat mental illness)
- Sublingual nitrates (used to treat angina and heart failure)
- Thyroid hormones (used to treat thyroid disorders). ↳ Ingresso nella GUK e senso di alimentazione ↑

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

**Pregnancy, breast-feeding and fertility**  
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not take this medicine without consulting your doctor.

**Driving and using machines**  
Doxepin capsules may make you feel drowsy. You should not drive or use machines when you take this medicine.

**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 medicinal product.  
Doxepin 25mg Capsules contains sunset yellow FCF (E110) and amaranth (E123) which may cause allergic reactions.

**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.

- Swallow the capsules whole with a glass of water.
- 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 your doctor will usually prescribe you a lower dose.
- 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.

**Use in children and adolescents:**  
Doxepin capsules are not recommended for children under 18 years.

**If you take more Doxepin capsules than you should:**  
Too many capsules at once can be dangerous. Sign 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 think that you, or any other person, have taken too many capsules, contact your doctor or hospital casualty department immediately. Take any remaining capsules and this leaflet with you so that the medical staff know exactly what you have taken.

**If you forget to take Doxepin capsules**  
If you miss a dose, wait until your next dose. Do not take the dose you have missed. You can then carry on as before.

**If you stop taking Doxepin capsules**  
You should always check with your doctor before you stop treatment. Your doctor may want 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. 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**

**Dimensions and Orientation:**  
Max. 215 mm (total height)  
Min. 170 mm (text area height)  
A = Min. 6 mm (margin)  
BAR INPUT (top and bottom)  
Linea di piega (fold line)

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.

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 trouble you, 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 heartbeat (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 capsules. 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 tests 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.

**It is important to tell your doctor or pharmacist if you suffer any of these or any other undesirable effects which are not listed above.**

#### 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](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. The expiry date refers to the last day of that month.

Doxepin 25 mg capsules: Do not store above 25°C  
Doxepin 50 mg capsules: Do not store above 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 protect the environment.

#### 6. Contents of the pack and other information

##### What Doxepin capsules contain


**Doxepin 25 mg capsules** – Each capsule contains 25 mg doxepin. Other ingredients: lactose monohydrate, maize starch and magnesium stearate. The gelatin capsules are coloured with titanium dioxide (E171), erythrosine (E127), sunset yellow (E110), patent blue V (E131), amaranth (E123).  
**Doxepin 50 mg capsules** – Each capsule contains 50 mg doxepin. Other ingredients: lactose monohydrate, maize starch and magnesium stearate. The gelatin capsules are coloured with titanium dioxide (E171), erythrosine (E127), patent blue V (E131).

##### What Doxepin capsules look like and contents of the pack

Doxepin 25 mg capsules are presented as red/dark blue capsules.  
Doxepin 50 mg capsules are presented as dark blue/dark blue capsules.  
The capsules are provided in blister packs containing 28 capsules.

##### Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 01/2023 

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