

Package leaflet: Information for the user

Sinepin (doxepin) 25mg and 50mg Capsules

doxepin Hydrochloride

Read all of this leaflet carefully before you start taking your 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 Sinepin is and what it is used for
2. What you need to know before you take Sinepin
3. How to take Sinepin
4. Possible side effects
5. How to store Sinepin
6. Contents of the pack and other information

1. What Sinepin is and what it is used for

The name of this medicine is Sinepin. The active ingredient is doxepin hydrochloride.

Sinepin 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, Sinepin 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 Sinepin

Do not take Sinepin Capsules if:

- You have ever had an allergic reaction to tricyclic antidepressants, doxepin, or any of the inactive ingredients of Sinepin Capsules (see 'Further information' section)
- 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 Sinepin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sinepin 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
- have depression or other conditions that are treated with antidepressants.

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

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

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.

Sinepin with alcohol

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

Sinepin 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.

3. How to take Sinepin

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 Sinepin 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 Sinepin 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 Sinepin 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 Sinepin for 2-3 weeks before you start to feel better.

- You must keep taking Sinepin 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.

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.

Sinepin 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
- Nausea
- Vomiting
- Indigestion
- Diarrhoea
- Constipation

Uncommon (may affect up to 1 in 100 people)

- Blurred vision
- Worsening of asthma
- Ringing or buzzing in the ears
- Chills
- Tiredness
- Flushing
- Weakness
- Skin rash
- Itching
- Face swelling
- Hair loss from the scalp
- Loss of appetite
- Fast heartbeat
- Excessive sweating
- High fever

Rare (may affect up to 1 in 1000 people)

- Dizziness
- Headache
- Difficulty in passing urine
- Swelling of testicles
- 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)
- Agitation
- Confusion
- Shakiness
- Trembling
- Changes in sex drive
- Numbness in the hands or feet

- Blood disorders: these may cause fever or chills and painful ulceration in the mouth or rectum
- Weight gain
- Feeling of pins and needles
- Abnormal blood tests results i.e.- change in blood sugar levels, lower sodium content of blood and low blood cell count.
- Unpleasant taste
- Stomach upset

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

Reporting of side effects

If you or your child 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 Sinepin

Do not take Sinepin after the date stamped on the pack. The expiry date refers to the last day of the month. Sinepin should be kept in a cool, dry place (below 25°C).

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

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 Sinepin Capsules contain

The capsules are free of gluten and sucrose.

Sinepin 25mg Capsule. Each capsule contains 25mg doxepin. Other ingredients: lactose, maize starch, magnesium stearate and sodium lauryl sulphate. The gelatin capsules are coloured with amaranth (E123), erythrosine, (E127), patent blue V (E131), sunset yellow (E110) and titanium dioxide (E171).

Sinepin 50mg Capsule. Each capsule contains 50mg doxepin. Other ingredients: lactose, maize starch, magnesium stearate and sodium lauryl sulphate. The gelatin capsules are coloured with erythrosine, (E127), patent blue V (E131) and titanium dioxide (E171).

What Sinepin Capsules look like and the contents of the pack

Sinepin 25mg Capsules (blue and red) come in packs of 28.

Sinepin 50mg Capsules (blue) come in packs of 28.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Marlborough Pharmaceuticals Ltd.

Sovereign House,

Miles Gray Road, Basildon,

Essex SS14 3FR, United Kingdom

Manufacturer

Allphamed PHARBIL GmbH

Hildebrandstrasse 12, D-37081 Gottingen, Germany

This leaflet does not contain all the information about this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

For information in large print, tape, CD or Braille, telephone 01279 406759.

This leaflet was last revised in May 2021