

Package leaflet: Information for the patient

Cinnarizin ABR 25 mg tablets

cinnarizine

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

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1. What Cinnarizin ABR is and what it is used for

Cinnarizine inhibits the transport of calcium ions through cell membranes, especially in the smooth muscle cells of vessels and thus causes them to expand. It reduces the excitability of the balance center. It increases cell resistance to lack of oxygen. It has no significant effect on blood pressure and heart rate.

Cinnarizine ABR is used as a supportive treatment for symptoms related to balance disorders, tinnitus, uncontrolled flickering and movement of the eyeball (nystagmus), nausea, vomiting, and the prevention of so-called travel sickness.

2. What you need to know before you take Cinnarizin ABR

Do not take Cinnarizin ABR if:

- you are allergic to cinnarizine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cinnarizin ABR.

Cinnarizine should be used with caution and as an exception in patients with Parkinson's disease. Your doctor will decide whether the expected treatment effect outweighs the risk of worsening the disease.

The product should be used with caution in patients with low blood pressure, closed-angle glaucoma, urinary retention of different origin.

Because cinnarizine undergoes extensive degradation in the liver and is subsequently excreted by the kidney, the product is used with particular care in patients with liver and kidney disease. With long-term treatment, your doctor will determine what laboratory tests need to be done regularly.

Other medicines and Cinnarizin ABR

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

When used with cinnarizine, the action of medicines used to suppress the nervous system, medicines used to treat depression (tricyclic antidepressants) and alcohol may be enhanced. When used concurrently, cinnarizine enhances the effects of medicines used to treat high blood pressure (antihypertensive agents).

Drugs that expand the vessels enhance the action of the product. When co-administered with atropine and other similar products, the effect of cinnarizine is increased.

As a result of its specific effects, cinnarizine may change skin test results used to diagnose allergy, so treatment with the product should be discontinued at least 4 days before the test.

Cinnarizine ABR with food and drink

There is no evidence of the need for a special diet or restrictions on certain types of food and drink during treatment with the product.

Alcohol consumption should be avoided because of it may potentiate the effects of cinnarizine. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

Pregnancy

Cinnarizine is not known to cause harm or any other adverse effects on the fetus in animals. Its safe use has not been established in pregnant women, so treatment with the product should not be initiated in these cases.

If pregnancy occurs, you should tell your doctor who will decide whether to continue treatment.

Breastfeeding

The safe use of cinnarizine in breast-feeding women has not been established, and therefore breast-feeding should not be initiated or, if necessary, breastfeeding should be discontinued during this period.

Driving and using machines

The administration of the product to drivers, machine operators or those performing activities requiring high concentration of attention and adequate coordination will be carefully considered by your doctor. It is known that in some cases, especially at the beginning of treatment or at high doses, cinnarizine can cause drowsiness, loss of coordination, confusion.

Cinnarizine ABR contains wheat starch and lactose

Cinnarizine ABR contains wheat starch. Patients with a wheat allergy (other than celiac disease) should not take this product. Suitable for people with celiac disease.

This product contains lactose (milk sugar), making it unsuitable for people with congenital or acquired intolerance to some sugars. If you have been told by your doctor that you have such an intolerance, ask your doctor for advice before taking this product.

3. How to take Cinnarizin ABR

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

Adults

Nausea, dizziness, coordination disturbances due to illness of the center of balance - 1 tablet 3 times daily.

Prevention of travel sickness - 1 tablet, taken 30 minutes - 1 hour before traveling and then 1 tablet every 6 hours, if needed.

Maximum daily intake should not exceed 9 tablets.

Take the tablets after a meal to avoid irritation of the stomach.

If you take more Cinnarizin ABR than you should

If you accidentally or intentionally take more than the prescribed dose, contact your doctor immediately or visit your nearest hospital. Do not use the medicine more often or for longer than prescribed to avoid overdose.

Acute overdose is manifested by vomiting, drowsiness, low blood pressure, shaking hands, loss of consciousness. It is possible for children to develop seizures.

If you forget to take Cinnarizin ABR

Do not use more than your prescribed dose to make up for a missed dose. Take the usual dose as soon as you have established that you've missed dose and then continue treatment as usual.

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.

The incidence of side effects is classified by the following criteria:

Very common: $\geq 1/10$

Common: $\geq 1/100$ to $<1/10$

Uncommon $\geq 1/1000$ to $<1/100$

Rare $\geq 1/10\ 000$ to $<1/1000$

Very rare $<1 / 10,000$, not known (frequency cannot be estimated from available data)

The following side effects are possible with cinnarizine treatment:

Investigations Rare	Weight gain
Nervous system disorders Common Rare Not known	Sleepiness Headache Movement Disorders *
Gastrointestinal disorders Uncommon Not known	Dry mouth Gastrointestinal disorders
Skin and subcutaneous tissue disorders Rare Very rare	Allergic skin reactions Lichen planus, lupus-like skin reactions
General disorders and administration site conditions Rare	Sweating
Hepatobiliary disorders Very rare	Jaundice as a result of bile retention
Psychiatric disorders Not known	Anxiety, depression

* These side effects are more common in the elderly who have taken the product for a long time. In these cases, treatment should be discontinued.

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

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 Sofia
Tel. +359 28903417
Website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cinnarizin ABR

Store below 25°C.

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.

Do not use Cinnarizine ABR if you notice a change in the appearance of the tablet.

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 Cinnarizin ABR contains

- The active substance is cinnarizine. Each tablet contains 25 mg cinnarizine.
- The other ingredients are lactose monohydrate, wheat starch, povidone, silica, colloidal anhydrous; magnesium stearate.

What Cinnarizin ABR looks like and contents of the pack

Cinnarizine ABR 25 mg tablets are white or off-white, round, biconvex tablets.

Types of packs

10 tablets in a blister. 5 blisters per carton.

50 tablets in a blister. 2 blisters per carton.

Marketing Authorisation Holder

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Manufacturer

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