

PACKAGE LEAFLET: INFORMATION FOR THE USER

Arlevert 20 mg / 40 mg tablets cinnarizine / dimenhydrinate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Arlevert is and what it is used for
2. Before you use Arlevert
3. How to use Arlevert
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6. Further Information

1. What Arlevert is and what it is used for

Arlevert contains two active ingredients. One is cinnarizine and one is dimenhydrinate. The two substances belong to different groups of medicines. Cinnarizine is part of a group called calcium antagonists. Dimenhydrinate belongs to a group called antihistamines.

Both substances work by reducing symptoms of vertigo (a feeling of dizziness or 'spinning') and nausea (feeling sick). When these two substances are used together they are more effective than when each one is used on its own.

Arlevert is used for the treatment of various kinds of vertigo. Vertigo can have a number of different causes. Using Arlevert can help you carry on with daily activities that are difficult when you have vertigo.

2. Before you use Arlevert

Do not use Arlevert if you:

- are under the age of 18 years.
- are allergic (hypersensitive) to cinnarizine, dimenhydrinate or diphenhydramine or any of the other ingredients. (Go to section 6. Further Information, for a list of the other ingredients).
- are allergic to any other antihistamines (such as astemizole, chlorpheniramine and terfenadine, used as allergy medicines). You should not take this medicine unless you have been told to by your doctor.
- suffer from angle-closure glaucoma (a specific type of eye disease),
- have epilepsy,
- have increased pressure in the brain (e.g. due to a tumour),
- suffer from alcohol abuse,
- have prostate problems which cause difficulty in urinating,
- have liver or kidney failure.

Take special care with Arlevert

Tell your doctor if you suffer from:

- low or high blood pressure,
- raised pressure in the eye,
- obstruction in the bowels,
- enlarged prostate,
- overactive thyroid,
- severe heart disease,
- Parkinson's disease.

The use of Arlevert may make these conditions worse. Arlevert may still be suitable for you but your doctor may need to take these facts into account.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. Arlevert may interact with other medicines that you are taking.

Arlevert can make you tired or sleepy when taken with the medicines listed below:

- barbiturates (medicines that are often taken to calm you down),
- narcotic analgesics such as morphine (strong painkillers such as morphine),
- tranquillisers (a type of medicine used to treat depression and anxiety),
- monoamine oxidase inhibitors (used to treat depression and anxiety).

Arlevert may increase the effects of the following medicines:

- tricyclic antidepressants (used to treat depression and anxiety),
- atropine (a medicine that relaxes muscles and is often used to examine your eye),
- ephedrine (can be used to treat cough or blocked nose),
- procarbazine (a medicine used to treat some kinds of cancer),
- medicines taken to lower blood pressure.

Aminoglycosides (a type of antibiotic) can damage the inner ear. If you take Arlevert you may not notice that this damage is happening.

You should not use Arlevert with drugs that are used to correct problems with your heart beat (anti-arrhythmics).

Arlevert may also change the way your skin reacts to allergy tests.

Taking Arlevert with food and drink

Take Arlevert after a meal. Arlevert can cause indigestion that can be reduced by taking the tablets after meals. Do not drink alcohol while using Arlevert because it may make you tired or sleepy.

Pregnancy and breast feeding

Do not take Arlevert if you are pregnant or are breast-feeding.

Driving and using machines

Arlevert may make you feel sleepy. If this occurs you should not drive or operate machinery.

3. How to use Arlevert

Always take Arlevert exactly as your doctor has told you. You should check

with your doctor or pharmacist if you are not sure.

The usual dose is: one tablet three times daily, with some liquid after meals. Swallow the tablet whole, do not chew.

Usually you will take Arlevert for up to 4 weeks. Your doctor will tell you if you need to take Arlevert for any longer.

If you take more Arlevert than you should:

If you accidentally take too many tablets or if a child takes some you should seek medical advice urgently.

If you take too much Arlevert you may become very tired, dizzy and shakey. Your pupils might dilate and you may not be able to urinate. Your mouth may feel dry, your face flush, you may have a faster heart rate, fever, sweat and have a headache.

If you have taken a massive amount of Arlevert you could have fits, hallucinations, high blood pressure, feel shakey, get excited, and find it difficult to breathe. Coma could occur.

If you forget to take a dose of Arlevert

If you forget to take a tablet of Arlevert just miss out that tablet. Take the next tablet of Arlevert the next time when you would usually take it. Do not take twice as much to catch up on the tablet you missed.

If you stop taking Arlevert

Do not stop taking Arlevert before your doctor tells you to. You are likely to have the symptoms of vertigo again (dizziness and 'spinning') if you stop treatment too soon.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Arlevert can cause side effects, although not everybody gets them.

Side effects which may **commonly occur** (less than 1 in 10 patients treated): drowsiness, dry mouth, headache, and stomach pain. These are usually mild and disappear within a few days even if you keep taking Arlevert.

Uncommon side effects (occurring in less than 1 in 100 patients treated): sweating, reddening of the skin, indigestion, nausea (feeling sick), diarrhoea, nervousness, cramps, forgetfulness, tinnitus (ringing in the ear), paraesthesia (tingling of the hands or feet), tremor (shaking).

Rare side effects (occurring in less than 1 in 1,000 patients treated): impaired vision, allergic reactions (e.g. skin reactions), light sensitivity, and difficulty in urinating.

Very rarely (occurring in less than 1 in 10,000 patients treated): white blood cell and platelet counts may be lowered, and blood cells may be severely reduced, which can cause weakness, bruising or make infections more likely.

In case of infections with fever and serious deterioration of your general condition, see your doctor and tell him about your medicine.

Other possible reactions which may occur with this type of medicine include:

weight gain, constipation, tightness of the chest, jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems), worsening of an angle-closure glaucoma (an eye disease with increased pressure inside the eye), uncontrollable movements, unusual excitement and restlessness (especially in children), severe skin reactions.

If any of the above side effects gets serious or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. How to store Arlevert

Keep Arlevert out of the reach and sight of children.

Do not use the tablets after the expiry date printed on the box.

This medicinal product does not require any special storage conditions.

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. Further Information

What Arlevert contains

The active substances of Arlevert are: cinnarizine 20 mg and dimenhydrinate 40 mg.

The other ingredients are: micro-crystalline cellulose, maize starch, talc, hypromellose, colloidal anhydrous silica, magnesium stearate and croscarmellose sodium.

What Arlevert looks like and contents of the pack

Arlevert tablets are round white tablets marked with an 'A'. They are available in packs containing 20, 50 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer:



HENNIG ARZNEIMITTEL
GmbH & Co. KG
Liebigstrasse 1-2
65439 Flörsheim am Main
Germany

Is this leaflet hard to see or read? Phone 01276 671166. Ask for help.

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