

PACKAGE LEAFLET: INFORMATION FOR THE USER
Arlevert® 20 mg/40 mg tablets
(cinnarizine/dimenhydrinate)

The name of your medicine is Arlevert 20mg/40mg Tablets but will be referred to as Arlevert throughout the remainder of this leaflet.

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.

What is in this leaflet

- 1. What Arlevert is and what it is used for
- 2. What you need to know before you take Arlevert
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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 in adults. Vertigo can have a number of different causes. Taking Arlevert can help you carry on with daily activities that are difficult when you have vertigo.

2. What you need to know before you take Arlevert

Do not take Arlevert if you:

- are under the age of 18 years.
- are allergic to cinnarizine, dimenhydrinate or diphenhydramine or any of the other Ingredients of this medicine (listed in section 6).
- 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,
- suffer from liver or kidney failure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Arlevert if you suffer from:

- low or high blood pressure,
- raised pressure in the eye,
- obstruction in the bowels,
- an enlarged prostate,
- an 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.

Other medicines and Arlevert

Tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines.

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

Amino glycosides (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 take 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.

Arlevert with food and drink

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

Pregnancy, breast-feeding and fertility

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

Driving and using machines

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

3. How to take 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 recommended 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 shaky. 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 shaky, get excited, and find it difficult to breathe. Coma could occur.

If you forget to take 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 a double dose to make up for a forgotten tablet.

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common side effects (affect up to 1 in 10 people): 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 (affect up to 1 in 100 people): 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 (affect up to 1 in 1,000 people): impaired vision, allergic reactions (e.g. skin reactions), light sensitivity, and difficulty in urinating.

Very rare side effects (affect fewer than 1 in 10,000 people): white blood cell and platelet counts may be lowered, and red blood cells may be severely reduced, which can cause weakness, bruising or make infections more likely. If you suffer from infections with fever and serious deterioration of your general health, see your doctor and tell him about your medicine.

Other possible reactions (frequency cannot be estimated from the available data) 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.

Reporting of side effects:

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

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

5. How to store Arlevert

Keep out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.

If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

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 Arlevert contains

Each Arlevert tablet contains 20mg cinnarizine and 40mg dimenhydrinate. The other ingredients are: microcrystalline 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' on one side and blank on the other side.

Arlevert 20 mg/40 mg tablets are available in packs containing 96 tablets.

POM

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This product is manufactured by Hennig Arzneimittel GmbH & Co. KG, Flörsheim am Main, Germany and procured from within the EU and repackaged by the Product licence Holder:

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