

Package leaflet: Information for the user

Arlevert 20 mg/40 mg tablets

cinnarizine/dimenhydrinate

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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
3. How to take Arlevert
4. Possible side effects
5. How to store Arlevert
6. Contents of the pack and other information

1. What Arlevert is and what it is used for

Arlevert contains two active ingredients. One is cinnarizine and the other 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
- if you are allergic to cinnarizine, dimenhydrinate or diphenhydramine or any of the other ingredients of this medicine (listed in section 6)
- if you 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.
- if you suffer from angle-closure glaucoma (a specific type of eye disease)
- if you have epilepsy
- if you have increased pressure in the brain (e.g. due to a tumour)
- if you suffer from alcohol abuse
- if you have prostate problems which cause difficulty in urinating
- if you suffer from liver or kidney failure.

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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 (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)
- medicines taken to lower blood pressure.

Procarbazine (a medicine used to treat some kinds of cancer) may increase the effect of Arlevert.

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, drink and alcohol

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

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.

Driving and using machines

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

Arlevert contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Arlevert

Always take this medicine exactly as your doctor or pharmacist has told you. 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, pharmacist or nurse.

4. Possible side effects

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

Common side effects (may 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 (may 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 (may 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 (may affect up to 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Website: www.hpra.ie

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

5. How to store Arlevert

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 blister and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater. 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

- The active substances are: cinnarizine (20 mg) and dimenhydrinate (40 mg).
- 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 are round, biconvex, white to pale yellow tablets embossed with an 'A' on one side, with a diameter of 8 mm. They are available in packs containing 20, 50 or 100 tablets. Tablets are packed in PVC/PVDC/Aluminium blisters containing 20 or 25 tablets, as appropriate. 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

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria:	Arlevert 20 mg/40 mg Tabletten			
Belgium, Luxembourg:	Arlevertan 20 mg/ tabletten/comprimés/Tabletten	40	mg	
Bulgaria:	Arlevert 20 mg/40 mg таблетки			
Cyprus, Greece:	Arlevert 20 mg/40 mg δισκία			
Czech Republic	Arlevert 20 mg/ 40 mg tablety			
Denmark, Sweden:	Arlevert 20 mg/40 mg tableter			
Estonia:	Arlevert 20 mg/40 mg tabletid			
Finland:	Arlevert 20 mg/40 mg tabletit			
Germany:	Arlevert 20 mg/40 mg Tabletten; Cinnarizin Dimenhydrinat Hennig 20 mg/40 mg Tabletten			
Hungary:	Arlevert 20 mg/ 40 mg tableta			
Ireland, United Kingdom (Northern Ireland):	Arlevert 20 mg/40 mg tablets			
Italy:	Arlevertan 20 mg/40 mg compresse			
Latvia:	Arlevert 20 mg/40 mg tabletes			
Lithuania:	Arlevert 20 mg/40 mg tabletés			

Poland:	Arlevert 20 mg + 40 mg tabletki
Portugal:	Arlevert 20 mg + 40 mg comprimidos
Romania	Arlevert 20 mg/40 mg comprimate
Slovak Republic	Arlevert 20 mg/40 mg tablety
Slovenia:	Arlevert 20 mg/40 mg tablete
The Netherlands:	Arlevert 20 mg/40 mg tabletten

This leaflet was last revised in 07/2021.