

## **Package leaflet: Information for the patient**

### **Azalonum 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 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 Azalonum is and what it is used for
2. What you need to know before you take Azalonum
3. How to take Azalonum
4. Possible side effects
5. How to store Azalonum
6. Contents of the pack and other information

#### **1. What Azalonum is and what it is used for**

Azalonum 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.

Azalonum is used for the treatment of various kinds of vertigo in adults. Vertigo can have a number of different causes.

#### **2. What you need to know before you take Azalonum**

##### **Do not take Azalonum:**

- 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 Azalonum 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 Azalonum may make these conditions worse. Azalonum may still be suitable for you but your doctor may need to take these facts into account.

### **Other medicines and Azalonum**

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

Azalonum may interact with other medicines that you are taking.

### **Azalonum 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)

### **Azalonum 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 cinnarizine/dimenhydrinate.

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

You should not take Azalonum with drugs that are used to correct problems with your heart beat (anti-arrhythmics). Azalonum may also change the way your skin reacts to allergy tests.

### **Azalonum with food, drink and alcohol**

Azalonum can cause indigestion that can be reduced by taking the tablets after meals. Do not drink alcohol while taking Azalonum 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.

Azalonum should not be used by pregnant or breastfeeding women.

### **Driving and using machines**

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

## **3. How to take Azalonum**

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. Swallow the tablet with some liquid after meals.

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

#### **Use in children and adolescents**

This medicine is not recommended in children or adolescents under the age of 18 years because the effects of the medicine in children and adolescents are not known.

#### **If you take more Azalonum 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 Azalonum 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 Azalonum 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 Azalonum**

If you forget to take a tablet of Azalonum just miss out that tablet. Take the next tablet of Azalonum 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 Azalonum**

Do not stop taking Azalonum 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,
- stomach pain.

These are usually mild and disappear within a few days even if you keep taking Azalonum

**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, or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [to be completed nationally].

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

## **5. How to store Azalonum**

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 medicinal product does not require any special storage conditions.

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 Azalonum contains**

- The active substances are: 20 mg cinnarizine and 40 mg dimenhydrinate.
- The other ingredients are: Cellulose microcrystalline, Croscarmellose sodium, Maize Starch, Hypromellose, Silica, colloidal anhydrous, Talc and Magnesium Stearate.

**What Azalonum looks like and contents of the pack**

White to off white, round, biconvex tablets with diameter 8 mm

They are available in blister packs containing 20, 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:****Marketing Authorisation Holder**

[To be completed nationally]

**Manufacturer:**

Medochemie Ltd, Central Factory, 1-10 Constantinoupoleos Street, 3011 Limassol, Cyprus

Medochemie Ltd, Factory AZ, 2 Michael Erakleous Street, Agios Athanassios Industrial Area,

Agios Athanassios, 4101 Limassol, Cyprus

**This medicinal product is authorised in the Member States of the EEA under the following names:**

**This leaflet was last revised 13 July 2020**