


Pizotifen 0.5mg and 1.5mg tablets



Read all of this leaflet carefully before you start taking your medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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1 What Pizotifen tablets are and what they are used for

Pizotifen belongs to a group of medicines called antihistamines or antiserotonin agents. These work by blocking chemicals that act on the blood vessels in the brain. Pizotifen tablets may be used to prevent headaches including migraine or cluster headaches.

2 Before you take

Do not take Pizotifen tablets to stop a migraine once one has started.

Do not take Pizotifen tablets and tell your doctor if you:

- are **allergic** (hypersensitive) to pizotifen or any of the other ingredients (see section 6).
- are taking monoamine oxidase inhibitors (MAOIs)

Check with your doctor or pharmacist

before taking Pizotifen tablets if you have:

- **glaucoma**
- any condition that may cause **retention of urine** such as an enlarged prostate gland
- **kidney** problems
- a history of **epilepsy**

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. Especially:

- medicines to help you sleep or relax (eg nitrazepam, diazepam or amobarbital sodium)
- antihistamines (including common cold preparations)
- medicines to lower blood pressure (eg guanethidine)
- medicines to treat depression, patients taking monoamine oxidase inhibitors (MAOIs) should not take Pizotifen tablets.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Pizotifen tablets may make you feel drowsy, make sure you are not affected before you drive or operate machinery.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains **lactose**.

3 How to take

Always take Pizotifen tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

You are advised **not** to drink alcohol with these tablets.

Swallow the tablets **with water**.

Doses:

- **Adults and elderly:** 1.5mg a day taken as a single dose at night or in three divided doses. Dosage should be adjusted up to a maximum of 4.5mg a day. Up to 3mg may be given as a single daily dose.
- **Children aged 7 years and over (do not use the 1.5mg tablet for this age group):** Daily dose up to a maximum of 1.5mg should be taken in divided doses using the 0.5mg tablets. A maximum single dose of 1mg can be given at night.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include drowsiness, dizziness, confusion, fits or excitement (particularly in children), difficulty in breathing or controlling movements, fast heart beat, low blood pressure, dry mouth, feeling or being sick, blueness of the skin, coma or respiratory paralysis.

If you forget to take the tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking the tablets

Talk to your doctor before you stop taking the tablets and follow their advice.

4 Possible side effects

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

Contact your doctor at once if you notice the following signs of an allergic reaction: rash, itching or swelling of the face, lips, throat or tongue.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Very common** (more than 1 in 10 users): increased appetite which may lead to weight gain.
- **Common** (less than 1 in 10 users): drowsiness, sleepiness, dizziness, dry mouth, feeling sick, tiredness.

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- **Uncommon** (less than 1 in 100 users): constipation.
- **Rare** (less than 1 in 1,000 users): pins and needles, muscle and joint pain, depression, anxiety, agitation, aggression, hallucinations, difficulty sleeping, sleep disorders.
- **Very rare** (less than 1 in 10,000 users): fits. Excitement in children may also occur.

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 the Yellow Card Scheme at: 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

Keep out of the reach and sight of children. Do not store above 25°C.

Do not use Pizotifen tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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 to protect the environment.

6 Further information

What Pizotifen tablets contain

- The active substance (the ingredient that makes the tablet work) is pizotifen. Each tablet contains either 0.725mg or 2.175mg of the active ingredient pizotifen hydrogen malate which is equivalent to 0.5mg and 1.5mg of pizotifen.
- The other ingredients are povidone, lactose, maize starch, magnesium stearate, microcrystalline cellulose (E460).
- The coating contains hypromellose, medium chain triglycerides, titanium dioxide (E171), iron oxide yellow (E172), iron oxide black (E172).

What Pizotifen tablets look like and contents of the pack

Pizotifen tablets are cream film-coated tablets.

Pack sizes are 28 tablets.

Marketing Authorisation Holder and manufacturer

Actavis, Barnstaple, EX32 8NS, UK

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