

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.

Index

- 1 What Pizotifen tablets are and what they are used for**
- 2 Before you take**
- 3 How to take**
- 4 Possible side effects**
- 5 How to store**
- 6 Further information**

1 What Pizotifen tablets are and what they are used for

Pizotifen tablets belong to a group of medicines called antihistamines or antiserotonin agents.

Pizotifen Tablets are a migraine treatment. They may help to stop the effects of certain naturally occurring substances in your body called "serotonin", "histamine" and "tryptamine" which are involved in causing some kinds of headache, including migraine.

Pizotifen Tablets have been prescribed for you by your doctor to help your migraine type headaches. If they are taken regularly they can help to prevent headaches or reduce the pain of cluster headaches, common and classical migraine. Pizotifen Tablets can stop some migraine attacks starting and help make other attacks less severe. They will not stop migraine attacks once they have started.

2 Before you take

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)
- **breast-feeding**.

Check with your doctor or pharmacist before taking Pizotifen tablets if you:

- have **glaucoma**
- have any condition that may cause **retention of urine** (e.g. an enlarged prostate gland)
- have **kidney** or **liver** problems
- have a history of **epilepsy**
- are **pregnant**

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 (including sleeping tablets, sedatives and antihistamine such as cold or hayfever tablets)
- antihistamines (including common cold preparations)
- medicines to lower blood pressure (e.g. guanethidine)

Pizotifen tablets and alcohol

Do not drink alcohol whilst taking this medicine.

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 2 years and over):** Children can take up to 1.5mg of pizotifen each day. This is three 0.5mg tablets. This is usually best given in two or three smaller doses. Do not use the 1.5mg tablets for children. Do not give them more than 1mg in a single dose. This is two 0.5mg tablets.
- **Renal and hepatic impairment:** Caution is required in patients with renal or hepatic impairment and dosage adjustment may be necessary.

Pizotifen tablets should not be given to children under 2 years of age.

Taking Pizotifen tablets

- Swallow the tablets whole. Have a drink with them if this helps you to swallow.
- If you take Pizotifen tablets once a day, take them in the evening a few hours before you go to bed as any drowsiness will help you to sleep.
- If you take your tablets in two or three doses, spread them evenly through the day.

Carry on taking your Pizotifen tablets even when you feel well. Your headaches may come back if you stop taking them. Do not stop taking them suddenly, or you may experience withdrawal symptoms, such as feeling anxious, shaking, insomnia, feeling sick and blackouts. Talk to your doctor if you want to stop taking your tablets.

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, fever, 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.

- **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.
- **Not known** (frequency cannot be estimated from the available data): If you have signs of yellowing of your skin or the whites of your eyes, abnormal darkening of the urine or unexplained nausea, vomiting and tiredness (signs of jaundice or hepatitis). Muscle cramps.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store

Keep out of the sight and reach 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 0.5mg are cream film-coated, round, biconvex tablets embossed "0.5" on one side.

Pizotifen tablets 1.5mg are cream film-coated, round, biconvex tablets embossed "1.5" on one side.

Pack sizes are 28 tablets.

Marketing Authorisation Holder and manufacturer

Accord, Barnstaple, EX32 8NS, UK

Date of revision: November 2020