

Package leaflet: Information for the user

Pizotifen 0.5 mg Tablets

Pizotifen 1.5 mg Tablets

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 effect not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pizotifen is and what it is used for
2. What you need to know before you take Pizotifen
3. How to take Pizotifen
4. Possible side effects
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1. What Pizotifen is and what it is used for

The name of your medicine is Pizotifen 0.5 mg or 1.5 mg Tablets (referred to as Pizotifen in this leaflet). Pizotifen contains the active ingredient pizotifen malate, which belongs to a group of medicines called anti-migraines.

Pizotifen is used to help block the actions of certain chemicals in the blood such as serotonin, histamine and tryptamine. These chemicals act on the blood vessels in the brain and are involved in causing types of headache, such as migraine.

If Pizotifen is taken regularly, it can help reduce the number and severity of headaches including the pain of cluster headaches and both common and classical migraine.

Pizotifen can also prevent some migraine attacks starting and helps make other attacks less severe but it should not be taken to relieve an attack once it has started.

2. What you need to know before you take Pizotifen

Do not take Pizotifen

- if you are allergic to Pizotifen or any of the other ingredients of this medicine (listed in section 6) or any other medicines that you may have taken to treat headaches.
- If you are taking monoamine oxidase inhibitors (MAOIs).
- Do not take Pizotifen to stop a migraine once one has started.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pizotifen if you

- suffer from kidney problems;
- are pregnant, trying to become pregnant or breast-feeding;
- have difficulty passing water;
- suffer with glaucoma (raised pressure in the eyes);
- suffer from epilepsy (fits);
- have an intolerance to lactose.

Children

Pizotifen is not recommended for children under 2 years of age.

Other medicines and Pizotifen

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines obtained without a prescription, and herbal medicines.

This is especially important if you are taking:

- medicines for depression, e.g. monoamine oxidase inhibitors (MAOIs); patients taking MAOIs should not take Pizotifen.
- medicines to treat anxiety or sleep disorders, e.g. tranquillisers and hypnotics;
- medicines for high blood pressure, e.g. anti-hypertensives;
- medicines to treat allergic reactions, e.g. anti-histamines;
- medicines to treat a cold.

Pizotifen and alcohol

It is advisable not to drink alcohol while you are taking this medicine as it may make you sleepy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Some people may feel dizzy or drowsy while they are taking this medicine. If you find that you do get dizzy or drowsy, do not drive or operate machinery, as impaired alertness may put yourself or others at risk.

Pizotifen contains lactose

Pizotifen tablets contain lactose. If you have been told that you have an intolerance to some sugars, talk to your doctor before taking Pizotifen.

3. How to take Pizotifen

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 dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take, and how often. Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

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.

Do not wait for a migraine before taking this medicine to treat the pain.

Take Pizotifen regularly to prevent a migraine or reduce the severity of the migraine.

The recommended dose is Adults and the elderly

1.5 mg daily (one 1.5 mg tablet at night or 0.5 mg tablets three times daily). Your doctor may increase the number of tablets you take up to a maximum of 4.5 mg (three 1.5 mg tablets or nine 0.5 mg tablets) if required. You may have been told to take your tablets daily as a single dose or you may have to take three smaller doses. Do not take more than 3 mg in a single dose (two 1.5 mg tablets or six 0.5 mg tablets). Do not exceed the maximum daily dose of 4.5 mg (three 1.5 mg tablets or nine 0.5 mg tablets).

Use in children

Pizotifen is not recommended for children under 2 years of age. For children over 2 years of age, at first, the dose may be 0.5 mg daily. This may be taken at night. The dose can be gradually increased to a maximum dose of 1.5 mg daily (three 0.5 mg tablets). This is usually best given in two or three smaller doses.

The maximum single dose is 1 mg (two 0.5 mg tablets). DO NOT give your child Pizotifen 1.5 mg Tablets.

If you take more Pizotifen than you should

If you accidentally take too much of your medicine, tell your doctor at once or contact your nearest hospital casualty department immediately. Take your medicine with you. Signs of an overdose include drowsiness, dizziness, confusion, fits or excitement (particularly in children), difficulty in breathing or controlling movements, fast heartbeat, low blood pressure, dry mouth, feeling or being sick, blueness of the skin, coma or respiratory paralysis.

If you forget to take Pizotifen

If you forget to take a dose, just take the next dose at the usual time. If you normally take Pizotifen Tablets several times a day you should take the last dose you missed as soon as you remember. Do not take it if there is less than 4 hours before your next dose, but go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten dose. Do not take more than your maximum daily dose.

Tell your doctor if you keep forgetting to take your tablets.

If you stop taking Pizotifen

Carry on taking Pizotifen 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. Do not change or stop the treatment without first asking your doctor. Your doctor may want you to reduce the dosage gradually before stopping completely.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Serious side effects

You are unlikely to get any of the following, but if you do, **tell your doctor immediately:**

- itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing or wheeziness.

These rare side effects (may affect up to 1 in 1,000 people) could indicate you are experiencing an allergic reaction. Stop taking the tablets and seek medical attention.

Other side effects

Very common side effects (may affect more than 1 in 10 people)

- Increased appetite with or without increase in weight

Common side effects (may affect up to 1 in 10 people)

- Feeling drowsy (although this may be avoided by taking the tablets at night);
- Feeling dizzy;
- Nausea (feeling sick);
- Dry mouth;
- Feeling tired (fatigue).

Uncommon side effects (may affect up to 1 in 100 people)

- Constipation.

Rare side effects (may affect up to 1 in 1,000 people)

- Difficulty in sleeping; sleep disorders
- Feeling depressed, anxious or aggressive;
- Seeing things (hallucinations);
- Pins and needles;
- Restlessness or excitability (in children);
- Muscle or joint pains.

Very rare side effects (may affect up to 1 in 10,000 people)

- Fits (seizures).

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 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 Pizotifen

Keep out of the sight and reach of children. Do not use this medicine after the expiry date that is stated on the carton or blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep in the original package.

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. Contents of the pack and other information

What Pizotifen contains

Each Pizotifen 0.5 mg Tablet contains 0.5 mg of the active ingredient pizotifen (as the malate).

Each Pizotifen 1.5 mg Tablet contains 1.5 mg of the active ingredient pizotifen (as the malate).

The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, povidone, magnesium stearate, colloidal anhydrous silica, hypromellose, macrogol, talc and titanium dioxide.

What Pizotifen looks like and the contents of the pack

Pizotifen 0.5 mg Tablets are white, round, film-coated, approximately 6mm in diameter, embossed with 'PZ' on one side.

Pizotifen 1.5 mg Tablets are white, round, film-coated, approximately 9mm in diameter, embossed with 'PZ 1.5' on one side.

They are packed in foil blister packs and are available in cartons of 28, 56 or 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical,
Sovereign House, Miles Gray Road,
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Manufacturer

Waymade PLC,
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PL 06464/1003 Pizotifen 1.5 mg Tablets

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