

Pizotifen Tablets 0.5 mg

Patient Information Leaflet

This medicine will usually be referred to just as Pizotifen Tablets in this leaflet.

What you need to know about Pizotifen Tablets

Your doctor has decided that you need this medicine to help treat your condition.

Please read this leaflet carefully before you start to take your medicine. It contains important information. Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Pizotifen Tablets are and what they are used for

Pizotifen Tablets are available in two different strengths containing either 0.5 mg or 1.5 mg of the active ingredient, pizotifen.

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. Things to consider before you start to take Pizotifen Tablets

Some people MUST NOT take Pizotifen Tablets. Talk to your doctor if:

- you think you may be allergic to pizotifen or to any of the other ingredients of Pizotifen Tablets. (These are listed at the end of the leaflet.)
- you are breast-feeding.

Pizotifen Tablets should not be given to children aged under 2.

You should also ask yourself these questions before taking Pizotifen Tablets:

- Do you have glaucoma (raised pressure in your eyes)?
- Do you ever have problems passing urine?
- Do you have kidney problems, especially kidney failure? (The medical term for this is renal failure.)
- Do you have liver problems? Pizotifen has been associated with abnormal results of liver function tests and possibly liver problems in a few patients. You may not notice any symptoms but if you notice yellowing of your skin or the whites of your eyes, abnormal darkening of the urine or unexplained nausea, vomiting and tiredness, tell your doctor straightaway. Your doctor may request blood tests to check and to monitor your liver function and may request that you stop the treatment if your liver problem is serious.
- Do you have epilepsy?
- Are you pregnant?
- Do you have an intolerance to some sugars? (The tablets contain a small amount of lactose and sucrose.)

If the answer to any of these questions is YES, tell your doctor or pharmacist because Pizotifen Tablets might not be the right medicine for you.

Are you taking other medicines?

- Remind your doctor if you are taking drugs called alpha- or beta-blockers because Pizotifen Tablets may affect the way they work.
- Anything that makes you sleepy may make you even sleepier if you are taking Pizotifen Tablets as well. This includes sleeping pills, sedatives and antihistamines such as cold and hayfever medicines. It also includes alcohol. It is best not to drink alcohol while you are taking Pizotifen Tablets.

Always tell your doctor about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

Will there be any problems with driving or using machinery?

Some people may feel drowsy and/or dizzy while they are taking Pizotifen Tablets. If this happens, you should not drive or do anything that requires you to be alert (such as operate tools or machinery) until such problems clear.

3. How to take Pizotifen Tablets

The doctor will decide what dose of Pizotifen Tablets you should take. Always take the tablets exactly as your doctor has told you to. 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. If you are not sure, ask your doctor or pharmacist. Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

With Pizotifen Tablets, you do not wait for a migraine and then treat the pain. You take it regularly to stop your migraines even beginning or to make them less severe.

Adults

- The usual dose is 1.5 mg of pizotifen each day. This is three 0.5 mg tablets. You may have been told to take your tablets once a day or as three smaller doses.
- Do not take more than 3 mg in a single dose (six 0.5 mg tablets). Do not take more than 4.5 mg (nine 0.5 mg tablets) in a day.

Children (aged over 2 years)

- Children can take up to 1.5 mg of pizotifen each day. This is three 0.5 mg tablets. This is usually best given in two or three smaller doses.
- Do not use the 1.5 mg tablets for children. Do not give them more than 1 mg in a single dose. This is two 0.5 mg tablets.

For children over 2 who find it difficult to take tablets Pizotifen is also available as an elixir (syrup).

Pizotifen Tablets and Elixir 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.

What if you forget to take a dose?

If you forget to take your tablets, do not worry. 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 double doses or take more than your maximum daily dose.

If you normally take one tablet each day take the dose as soon as you remember. Take your next dose as usual. Do not take more than your maximum daily dose.

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

What if you take too many tablets?

All tablets can be risky if you take too many. If you take too many Pizotifen Tablets at once, tell your doctor or hospital casualty department as soon as possible. Take your medicine pack with you so that people can see what you have taken.

If you stop taking Pizotifen

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. This is to prevent any worsening of your condition and reduce the risk of withdrawal symptoms such as depression, trembling, nausea, anxiety, generally feeling unwell, dizziness, sleep disorder and weight loss.

4. Possible side effects

Pizotifen Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects.

Some side effects can be serious

Stop taking the tablets and tell your doctor immediately if you notice any of the following rare symptoms:

- Symptoms of allergy such as a rash, itching or hives on the skin or swelling of the face.

The side effects listed below have also been reported:

More than 1 in 10 people have experienced:

Increase in appetite and weight gain. An increase in appetite may lead to an increase in bodyweight. If you feel hungrier than usual, try to fill up on fresh low calorie foods. These are much healthier than processed high calorie foods. Your doctor can give you advice about diet as some kinds of foods are known to trigger migraine.

Up to 1 in 10 people have experienced:

Drowsiness, tiredness, dizziness, dry mouth, nausea. Feeling drowsy is not usually a problem as you can take the tablets in the evening. The effect of making you drowsy will help you to sleep. You are less likely to feel drowsy after a few weeks, as you get used to the tablets.

Up to 1 in 100 people have experienced:

Constipation.

Up to 1 in 1,000 people have experienced:

Depression, excitability or restlessness, hallucinations (seeing, hearing or feeling things that are not there), sleep disturbances, insomnia, anxiety, tingling or numbness of the hands or feet, muscle or joint pain.

Very rarely (less than 1 in 10,000) people have experienced:

Convulsions (fits). Tell your doctor immediately if you have a fit.

Frequency: not known:

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.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Pizotifen Tablets

Keep your tablets in the pack they came in. Keep your tablets in a safe place, away from strong light.

Keep all medicines out of the reach and sight of children.

Do not take the tablets after their expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking Pizotifen Tablets, please take any unused tablets back to your pharmacist to be destroyed. Only keep the tablets if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Further information

Pizotifen Tablets 0.5 mg are ivory coloured printed SMG on one side, and they contain 0.5 mg of the active ingredient pizotifen (as 0.725 mg of pizotifen hydrogen malate). They come in blister packs of 60.

The tablets also contain the inactive ingredients lactose, starch, polyvinylpyrrolidone, magnesium stearate, talc, gum acacia, carnauba wax, sugar, printing wax, anhydrous colloidal silica and the colouring agents E171 (titanium dioxide) and E172 (iron oxide).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland.

Manufacturer

Novartis Pharmaceuticals UK Ltd, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, England, United Kingdom and Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, England, United Kingdom.

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