PATIENT INFORMATION LEAFLET
PIZOTIFEN 0.5 mg & 1.5 mg TABLETS BP
(pizotifen malate)

The name of this medicine is Pizotifen 0.5 mg & 1.5 mg Tablets BP, which will be referred to as Pizotifen Tablets throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. 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.

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1. WHAT PIZOTIFEN TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in this product is pizotifen malate, which is used to prevent migraine-type headaches, including cluster headaches, common and classical migraine. These work by stopping the effects of naturally occurring substances in the body which cause migraine-type headaches. Pizotifen can also prevent some migraine attacks starting and helps make other attacks less severe. Pizotifen does not help to relieve a migraine attack once it has started.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PIZOTIFEN TABLETS

Do not take Pizotifen Tablets if you:
- are **allergic to pizotifen malate**, or any of the **other ingredients** of this medicine (listed in section 6)
- are breast feeding

Pizotifen must not be given to children under the age of 2 years.

Warnings and Precautions
Talk to your doctor or pharmacist before you take Pizotifen Tablets if you:
- are pregnant, planning to become pregnant or suspect you are pregnant
- have glaucoma (raised pressure in your eyes causing visual problems, your field of vision will be limited) – your doctor will tell you if you have this
- have problems in passing urine
- have kidney problems
- have liver problems
- have epilepsy
- have an intolerance to some sugars

Other medicines and Pizotifen Tablets
Tell your doctor if you are taking or have recently taken any of the following medicines, as the effect of Pizotifen Tablets may be increased or decreased by other medicines and vice versa.
- medicines to treat anxiety or sleep disorders, e.g. tranquillisers and hypnotics
- medicines to treat allergic reactions, e.g. anti-histamines
- medicines to treat a cold
- medicines called alpha- or beta- blockers

It may still be alright for you to take Pizotifen Tablets and your doctor will be able to decide what is suitable for you. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking your medicine with food, drink and alcohol
Do not drink alcohol whilst taking this medicine.
Pizotifen Tablets should be swallowed with a glass of water and can be taken with or without food.

Pregnancy and breast-feeding
Do not use this medicine if you are pregnant, think you might be pregnant, planning to become pregnant or breast-feeding unless your doctor has told you to do so.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Pizotifen Tablets may make you feel drowsy, dizzy or affect your concentration. Do not drive or operate machines if you are affected.

Important information about some of the ingredients of Pizotifen Tablets
This product contains **lactose**. If you have been told by your doctor that you have **an intolerance to some sugars**, contact your doctor before taking this medicine.

3. HOW TO TAKE PIZOTIFEN TABLETS

Always take Pizotifen Tablets exactly as your doctor has told you to do so. You should check with your doctor or pharmacist if you are not sure.
Dosage:
The usual dosage for Pizotifen Tablets is:

Adults and elderly patients
The usual starting dose is 1.5 mg daily. This may be taken as one 1.5 mg tablet at night or as three divided doses of 0.5 mg tablets.
Do not take more than 3 mg (two 1.5 mg tablets or six 0.5 mg tablets) in a single dose.
Do not take more than 4.5 mg (three 1.5 mg tablets or nine 0.5 mg tablets) in a day.

Children (aged 2 years and over)
The usual dose can be up to 1.5 mg daily. This must be given as two or three smaller doses. Do not give children more than 1.0 mg in a single dose. DO NOT give your child Pizotifen 1.5 mg Tablets.

Special populations: *Renal and hepatic impairment*
Caution is required in patients with renal or hepatic impairment and dosage adjustment may be necessary.

Pizotifen Tablets are not recommended for children under 2 years.

Method of administration
Pizotifen Tablets should be swallowed with a glass of water. Keep taking the tablets until your doctor tells you to stop.

If you take more Pizotifen Tablets than you should
If you have accidentally taken more than the recommended or prescribed dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you.

The most common signs of overdose are a fall in blood pressure (causing dizziness and light-headedness), uncontrolled muscle movements, drowsiness, dry mouth, confusion, excitatory states (particularly in children), nausea (feeling sick), shortness in breath and a blue skin colour, vomiting (being sick), a forceful and rapid heart-beat, convulsions (particularly in children), coma and sudden stoppage of breathing.

If you forget to take Pizotifen Tablets
If you miss a dose do not worry. Take another as soon as you remember and then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Pizotifen Tablets
Do not stop taking Pizotifen Tablets even if your headaches stop, as they may come back if you stop taking the tablets. If you stop taking Pizotifen Tablets suddenly you may experience withdrawal symptoms. Your doctor will tell you how to reduce and then stop this medicine.

Withdrawal symptoms include tremor (shakes), insomnia (difficulty sleeping), anxiety, nausea (feeling sick) and loss of consciousness.

If you have any further questions about this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pizotifen Tablets can cause side effects, although not everybody gets them.
If you get any of the following symptoms after taking these tablets you **should contact your doctor or pharmacist immediately:**

- **any allergic reaction such as a rash, sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat**
- **urticaria (hives)**

The following side effects have also been reported:
Very common (affecting more than 1 in 10 people):
- increased appetite, weight increase

Common (affecting 1 to 10 people in 100):
- drowsiness or a strong desire to sleep
- fatigue (tiredness)
- dizziness
- nausea (feeling sick)
- dry mouth

Uncommon (affecting 1 to 10 people in 1,000):
- constipation

Rare (affecting 1 to 10 people in 10,000):
- depression
- restlessness (particularly in children)
- difficulty sleeping (insomnia) or sleep disturbances
- anxiety
- aggression
- agitation
- hallucinations (seeing, feeling and hearing things that are not there)
- 'pins and needles' or a sensation of tingling and prickling of skin
- muscle and joint pain

Very rare (affecting less than 1 person in 10,000):
- seizures (fits)

Unknown:
- hepatic enzyme increased, jaundice, hepatitis Muscle cramp

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 United Kingdom Yellow Card Scheme Website: 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 TABLETS

Keep all medicines out of the sight and reach of children.
Do not take this medicine after the expiry date (Exp.) stated. The expiry date refers to the last day of that month.
Do not store these tablets above 30ºC. Store in the original packaging. Keep in the outer carton.
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 Tablets contain:
The active ingredient is pizotifen malate. Each Pizotifen tablet contains 0.5 mg or 1.5 mg of pizotifen as pizotifen malate. The other ingredients are: lactose monohydrate, microcrystalline cellulose, maize starch, povidone K30, magnesium stearate, silicon dioxide, hypromellose, macrogol 6000, talc and E171.

What Pizotifen Tablets look like and the contents of the pack:
Pizotifen Tablets are white, round convex film-coated tablets.
Pizotifen 0.5mg tablets are marked 'P' on one side and plain on the other.
Pizotifen 1.5mg tablets are marked 'PZ' on one side and plain on the other.
Your medicine is available in packs of 28, 30, 56, 60, 84, 90, 112 and 120 (not all pack sizes may be marketed).

Marketing Authorisation Holder:
Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer responsible for batch release:
Kent Pharmaceuticals Limited, Unit 200, Westminster 42, Westminster Industrial Estate, Repton Road, Measham, Swadlincote, DE12 7DT, U.K.

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