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Leaflet

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nodes, trouble swallowing, skin rash, nausea, vomiting, dizziness, stomach cramps, joint pain, swelling of the face, lips, mouth, and tongue.
If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or health care provider.

5. How to store PZ-1/PZ-4 Tablets
Do not store above 30°C. Protect from light.
Keep out of the reach and sight of children.
Store in the original carton.
Do not use this medicine after the expiry date stated on the carton (MYYYY).
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 PZ-1 Tablets contains?
Each uncoated tablet contains:
Pimozide BP 1 mg
Excipients q.s.
This product contains "Lactose".
What PZ-4 Tablets contains?
Each uncoated tablet contains:
Pimozide BP 4 mg
Excipients q.s.
This product contains "Lactose".
What PZ-1 Tablets looks like and contents of the pack.
White, round, uncoated tablets having breakline on one side of each tablet and other side is plain.
What PZ-4 Tablets looks like and contents of the pack.
White, circular, flat uncoated tablets having breakline on one side of each tablet.
Shelf life: 36 months
Presentation:
Bulk pack of 30's & 240's Tablets
Distribution Category: Prescription Only Medicine (POM)

Marketing Authorisation Holder and Manufacturer
AGOG PHARMA LTD.
Plot No. 33, Sector-II, The Vasai Taluka Ind. Co-op. Estate Ltd., Vasai (E), Dist. Thane, INDIA.

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Package leaflet: Information for the user
PZ-1/ PZ-4 TABLETS
(Pimozide Tablets BP 1 mg/ 4 mg)

Read all of this leaflet carefully before taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptom are the same as yours.
- If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

What is in this leaflet?
1. What PZ-1/ PZ-4 Tablets are and what they are used for?
2. What do you need to know before you take PZ-1/ PZ-4 Tablets?
3. How to take PZ-1/ PZ-4 Tablets?
4. Possible Side Effects
5. How to store PZ-1/ PZ-4 Tablets?
6. Further information

1. What PZ-1/ PZ-4 Tablets are and what they are used for?
PZ-1/ PZ-4 tablets contain the active substance Pimozide.
Pimozide is a diphenylbutylpiperidine first-generation antipsychotic drug. It is used to treat symptoms of Tourette's syndrome. The exact way the medication works for Tourette's syndrome isn't known, but it lowers dopamine levels in the brain.
This is believed to help reduce tics. PZ-1/PZ-4 tablets are used:

- To treat symptoms of Tourette's syndrome.
- To treat schizophrenia.

2. What you need to know before you take PZ-1/ PZ-4 Tablets?
Do not take this medicine if,

- You are allergic (hypersensitive) to Pimozide.
- You have depressive disorder or Parkinson's syndrome.

Take special care with PZ-1/ PZ-4 Tablets
If you have

- CNS depression.
- Comatose states.
- Liver, heart or kidney disorder.
- Long QT syndrome.
- Blood dyscrasias.
- History of cardiac arrhythmias.

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- Seizures.
- Glaucoma.

Taking with other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.
Tell your doctor if you are taking any of these following medicines:

- Amiripityline, nortriptyline (used to treat symptoms of depression)
- Chlorpromazine (used to treat psychotic disorders such as schizophrenia or mania-depression in adults)
- Quinidine (used to treat and manage specific arrhythmias and malaria)
- Droperidol (used to treat nausea and vomiting)
- Azithromycin, erythromycin, moxifloxacin (used for bacterial infections)
- Fluconazole, Itraconazole (used for fungal infections)
- Tacrolimus (used for prophylaxis of organ rejection post transplant)
- Indinavir, nelfinavir, ritonavir, amprenavir (used to treat HIV)
- Mefloquine (used to treat malaria)
- Bosutinib (used to treat chronic myelogenous leukemia)

Taking PZ-1/ PZ-4 Tablets with food and drink
Avoid drinking grapefruit juice while taking pimozide. Grapefruit juice can increase levels of pimozide in your body and may increase the risk of side effects. You should also avoid the use of alcohol while being treated with pimozide. Alcohol can increase the nervous system side effects of pimozide such as dizziness, drowsiness and difficulty concentrating. Talk to your doctor or pharmacist for best advice on foods and drinks to avoid while taking PZ-1/PZ-4 tablets.
Pregnancy and breast-feeding
Talk to your doctor or pharmacist before taking this medicine if you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby.
Driving and using machine
Do not drive or use any tools or machines because pimozide can cause drowsiness.

3. How to take PZ-1/ PZ-4 Tablets?
Always take this medicine exactly as your doctor or health care provider has told you. You should check with your doctor or health care provider if you are not sure.

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Unless otherwise prescribed by the doctor, the recommended doses are:
Schizophrenia
By mouth.
Adult: Initially 2 mg daily, adjusted according to response, then increased in steps of 2-4 mg at intervals of not less than 1 week; usual dose 2-20 mg daily.
Elderly: Initially 1 mg daily, adjusted according to response, increased in steps of 2-4 mg at intervals of not less than 1 week; usual dose 2-20 mg daily.
Monosymptomatic hypochondriacal psychosis, Paranoid psychosis
By mouth.
Adult: Initially 4 mg daily, adjusted according to response, then increased in steps of 2-4 mg at intervals of not less than 1 week; maximum 16 mg per day.
Elderly: Initially 2 mg daily, adjusted according to response, increased in steps of 2-4 mg at intervals of not less than 1 week; maximum 16 mg per day.
If you take more PZ-1/ PZ-4 Tablets than you should
If you have accidentally taken more tablets in one day than your doctor has told you to, contact your doctor or pharmacist.
If you forget to take PZ-1/ PZ-4 Tablets
Do not take a double dose to make up for a forgotten dose if you forget to take these tablets.
If you stop taking PZ-1/ PZ-4 Tablets
Do not stop taking your tablets, even if you feel better. It is important to take the tablets as long as the doctor has told you to, otherwise your medicine might not work properly.
If you have any further questions on the use of this product, ask your doctor or health care provider.
PZ-1/ PZ-4 Tablet contains Lactose
Lactose is a type of sugar. If you have been told by a doctor that you cannot tolerate sugar, talk to your doctor or healthcare provider before taking this medicine.

4. Possible side effect:
Like all medicines, PZ-1/ PZ-4 tablets can cause side effects, although not every body gets them.
Most common side effects: Blurred vision, constipation, drowsiness, dry mouth, headache, restlessness, and weakness.
Serious side effects: Breathing problems, fever, swollen lymph

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