

PACKAGE LEAFLET: Information for the patient

PIPERAZINE

Tablets – 250 mg

(Piperazine adipate)

Read 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 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 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.

In this leaflet:

1. What Piperazine is and what it is used for
2. Before you take Piperazine
3. How to take Piperazine
4. Possible side effects
5. How to store Piperazine
6. Other information

1. WHAT PIPERAZINE IS AND WHAT IT IS USED FOR

Piperazine is an antihelmintic that acts against roundworms (*Ascaris lumbricoides*) and pinworms (*Enterobius vermicularis*). In roundworms, piperazine causes neuromuscular block leading to muscle paralysis of these parasites, which then are easily dislodged from their position by the movement of the gut and expelled in the faeces.

Piperazine 250 mg tablets are indicated in the treatment of ascariasis and enterobiasis.

Your doctor may have given Piperazine for a different purpose. Ask your doctor if you want to know why you were given Piperazine.

2. BEFORE YOU TAKE PIPERAZINE

Do not take Piperazine if:

- you are hypersensitive to piperazine or to any of the other excipients of Piperazine tablets;
- you suffer from epilepsy;
- you have severe renal impairment;
- you have liver impairment.

Take special care with Piperazine

Ask your doctor before taking Piperazine if:

- it will be used in patients with renal impairment (it should not be used when the impairment is severe);
- it will be used in patients with neurological disturbances;
- you are pregnant.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Piperazine. Please contact with your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Piperazine if you have been given any other drug during treatment.

- The antihelmintic effect of piperazine may be antagonised by pyrantel.
- There is the possibility of interaction of phenothiazines with piperazine.

Taking Piperazine with food and drinks

There are no data on the influence of food and drinks in the pharmacokinetics of Piperazine.

Pregnancy

Inform your doctor or pharmacist if you are pregnant or you are planning to become pregnant. It is reported that piperazine is teratogenic in rabbits and there are reported isolated cases of fetal malformations after use of piperazine in humans. For this reason, it is advised not to use it during pregnancy and particularly during the first trimester, unless treatment with piperazine is indispensable for the mother.

Breastfeeding

Piperazine passes into breast milk. Mothers should be advised to take the drug after breastfeeding and then not to breastfeed for 8 hours. During this period they should collect and discharge the milk which will be excreted at the normal feeding times.

3. HOW TO TAKE PIPERAZINE

Always take Piperazine tablets as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Piperazine are too strong or too weak, talk to your doctor or pharmacist.

The tablets should be swallowed with a glass of water (200 - 250 ml of water).

Dosage is given as follows:

Children up to 1 year: 200 mg, 2 - 3 times daily;

Children from 1 - 6 years: 200 - 400 mg, 2 - 3 times daily;

Children from 6 - 15 years: 400 - 500 mg, 2 - 3 times daily;

Children over 15 years and adults: 500 mg, 3 times daily.

Treatment continues for 1 week and piperazine is usually taken 2 hours before meals. In the treatment with loading doses (especially in ascariasis), on the first day are used 100 mg piperazine / kg of body weight, 2 hours before dinner, but no more than 3 g (i.e. 12 tablets). The same dose is used the second day on a fasting state (1 hour before breakfast). Usually it is advised that treatment with Piperazine be repeated after 6 weeks in ascariasis.

If you take more Piperazine

If you take more Piperazine than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Piperazine

If you forget a dose (or more doses), take the next dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose (doses).

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

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Piperazine may cause side effects, although not everybody manifests them. Piperazine is well tolerated in the recommended doses. Inform your doctor for the following side effects that may appear to you:

- nausea, vomiting, colics, diarrhea, abdominal pain, headache;
- allergic reactions (including urticaria, cutaneous rashes, bronchospasms and more rarely Stevens-Johnson syndrome and angioedema);
- more rarely are described dizziness, muscle incoordination, drowsiness, fatigue, ataxia, paraesthesia, mental confusion, choreiform movements, tremor, myoclonic contractions, convulsions and loss of reflexes in patients with neurological or renal impairment;
- temporary visual disturbances such as blurred vision and cataract formation, even though the last one has not yet been proved.

If any of the side effects worsens, or if you notice side effects not listed in this leaflet, please inform your doctor or pharmacist. When any of the above-mentioned side effects appears to you, treatment with Piperazine should be discontinued and you should consult your doctor or pharmacist.

5. HOW TO STORE PIPERAZINE

Keep away from children!

Do not use Piperazine after the expiry date.

Store below 25°C.

Store in the original packaging to protect it from light and humidity.

6. OTHER INFORMATION

What Piperazine contains

The active substance is piperazine adipate.

Each tablet contains 250 mg piperazine adipate.

The excipients are starch, microcrystalline cellulose, gelatin, sodium starch glycolate, magnesium stearate.

Content of the pack:

Carton box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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