

Package leaflet: Information for the patient

Inosipranol® 500 mg powder for oral solution Inosipranol® 1000 mg powder for oral solution

Inosine pranobex

Read all of this leaflet carefully before you start using 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 effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Inosipranol is and what it is used for
2. What you need to know before you take Inosipranol
3. How to take Inosipranol
4. Possible side effects
5. How to store Inosipranol
6. Contents of the pack and other information

1. What Inosipranol is and what it is used for

Inosipranol contains the active ingredient inosine pranobex, which is used to treat certain viral infections and to enhance the body's natural immunity and immune response to viral infections. The drug mainly affects the components of cellular immunity. It also has an anti-viral effect.

Inosipranol is used to stimulate your immune system to overcome viral infections, such as:

- influenza/viral respiratory infections;
- repeated/recurrent genital herpes;
- repeated/recurrent herpes simplex of the lips;
- herpes zoster (painful infection with vesicles along a nerve);
- varicella (chicken pox);
- measles (smallpox - respiratory tract infection with fever and skin rash);
- parotitis/mumps (a viral infection that can lead to swelling and pain in the parotid salivary glands);
- viral hepatitis;
- genital warts and other infections caused by the human papilloma virus;
- other viral infections, such as infectious mononucleosis (infection caused by Epstein-Bar virus), infection caused by cytomegalovirus;
- subacute sclerosing panencephalitis (a neurological disease of children and young people which affects the central nervous system).

2. What you need to know before you take Inosipranol

Do not take Inosipranol if:

- you are allergic to inosine pranobex or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from gout;
- if you have high levels of uric acid.

Warnings and precautions

Talk to your doctor or pharmacist before taking Inosipranol if:

- you know that you have gout or elevated uric acid levels;
- you know you have kidney stones;
- you suffer from kidney disease (you need to be monitored);
- You will need long-term treatment (you will need to have regular blood tests and a check on your kidney and liver function). Patients with long-term treatment may develop kidney stones.
- You notice signs of an allergic reaction, such as rash, itching, shortness of breath, or swelling of the face, lips, throat, or tongue. In such a case, stop treatment immediately and see your doctor.

Other medicines and Inosipranol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking any of the medicines listed below, tell your doctor as they may interact with Inosipranol:

- allopurinol or other medicines for gout;
- diuretics (dehydration drugs);
- drugs that suppress the immune system, e.g. after organ transplantation: azidothymidine (a drug for treatment of AIDS).

Pregnancy, breast-feeding and fertility

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

Inosipranol should not be taken during pregnancy and lactation unless your doctor considers it necessary.

Driving and using machines

Inosipranol does not affect the ability to drive and use machines.

3. How to take Inosipranol

Always use this medicine as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration

Inosipranol is intended for oral use.

- Open the sachet before use.
- Pour the contents of the sachet into a glass of water (cold or lukewarm) and, for better dissolution, stir the water into the glass.
- After reconstitution, the medicine should not be stored for future use.

Take this medicine with or without food at any time of the day.

Adults and the elderly (over 65 years)

The recommended daily dose is 50 mg/kg body weight, usually 3 g/day, up to a maximum of 4 g/day, administered in 3-4 evenly divided doses throughout the day (usually 2 sachets of 500 mg or 1 sachet of 1000 mg, 3-4 times a day during the day).

Children >1 year of age

The recommended daily dose is 50 mg/kg body weight given in 3-4 evenly divided doses throughout the day.

The daily dose of 4 g should not be exceeded.

Your doctor will determine the right dose for you, depending on your body weight and the type and severity of your illness and will advise you on how long to take the medicine. It is important that you

take the medicine throughout the period of your prescribed treatment, even if the symptoms persist before you finish all sachets.

If you take more Inosipranol than you should

There have been no reports of overdose so far. If you take more sachets than you should, please contact your doctor.

If you forget to take Inosipranol

If you miss a dose, take it as soon as you remember, unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Inosipranol

If you stop treatment, the desired effect will not be achieved or the symptoms may worsen again. Talk to your doctor before stopping treatment.

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.

You should contact your doctor immediately if you get:

- sudden wheezing;
- difficulty breathing and/or dizziness;
- swelling of the eyelids, face and throat;
- generalised rash and itching

The above-mentioned manifestations may be symptoms of serious allergic reactions, which, although very rarely, cannot be ruled out when taking this medicine.

The following side effects are possible when treated with this medicine:

Very common (may affect more than 1 in 10 patients)

- transient elevation of uric acid levels in blood and urine.

Common (may affect from 1 to 10 in 100 patients)

- increased levels of liver enzymes;
- increased levels of urea (waste product) in the blood;
- skin rash;
- itching;
- joint pain;
- vomiting;
- nausea;
- stomach pain
- fatigue;
- weakness (malaise);
- headache;
- dizziness (vertigo).

Uncommon side effects (may affect 1 to 10 in every 1000 patients):

- diarrhea;
- constipation;
- drowsiness;
- inability to sleep and impaired sleep (insomnia);
- nervousness;
- increased amount of urine (polyuria).

Not known (frequency cannot be estimated from available data):

- abdominal pain;
- swelling of the face, lips, eyelids or throat (angioedema);
- hives;
- allergic reaction affecting the whole body (anaphylactic reaction);
- dizziness;
- redness of the skin (erythema).

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

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 Sofia
Tel. +359 28903417
Website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Inosipranol

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the sachet and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Inosipranol contains

- The active substance is inosine pranobex. Each sachet contains 500 mg or 1000 mg of inosine pranobex.
- The other ingredient is mannitol, saccharin sodium, orange flavor.

What Inosipranol looks like and contents of the pack

White to off-white powder with orange flavour.

Inosipranol 500 mg powder for oral solution: paper/polyethylene/aluminium sachets packed in cartons containing 20, 30 and 50 sachets, together with a package leaflet.

Inosipranol 1000 mg powder for oral solution: paper/polyethylene/aluminium sachets packed in cartons containing 20 sachets, together with a package leaflet.

Marketing Authorisation Holder

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