

Package leaflet: Information for the patient

Inosipranol® 50 mg/ml syrup

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

1. What Inosipranol syrup 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;
- recurrent/recurrent genital herpes;
- recurrent/recurrent herpes simplex of the lips;
- herpes zoster (painful blistering infection along the nerve);
- aphthous stomatitis (inflammation of the lining of the mouth);
- chickenpox (hazelnut) and rubella - acute infectious diseases caused by a virus and manifested by a characteristic rash;
- measles (smallpox);
- parotitis/mumps (a viral infection that can cause swelling and pain in the parotid salivary glands);
- viral hepatitis (inflammation of the liver);
- genital warts and other infections caused by the human papilloma virus;
- other viral infections, such as infectious mononucleosis (Epstein-Barr virus infection), cytomegalovirus infection;
- subacute sclerosing panencephalitis (a neurological disease of children and young people that affects the central nervous system).

2. What you need to know before you use Inosipranol syrup

Do not use Inosipranol syrup 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 syrup

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 syrup:

- allopurinol or other medicines for gout;
- diuretics (dehydration drugs);
- drugs that suppress the immune system, e.g. after organ transplantation: zidovudine (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.

Inosipranol syrup contains methyl parahydroxybenzoate, propyl parahydroxybenzoate and sucrose

This medicine contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

A single dose of Inosipranol syrup over 10 ml contains > 5 g of sucrose, which should be considered in patients with diabetes mellitus.

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 use Inosipranol syrup

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

The dose you will take and the duration of treatment will be determined by your doctor depending on your body weight and the type and severity of your illness.

Adults and the elderly (over 65 years)

The recommended daily dose is 50 mg/kg body weight (1 ml/kg), usually 3 g/day, up to a maximum of 4 g/day, given in 3-4 evenly distributed doses throughout the day (usually 3-4 x 20 ml). daily in the waking hours).

The daily dose of 4 g should not be exceeded.

Children over 1 year of age

The recommended daily dose is 50 mg/kg body weight (1 ml/kg) administered in 3-4 evenly distributed doses throughout the day or according to the table below:

Body weight	Dosage
10 - 14 kg	3 x 5 ml
15 - 20 kg	3 x 5 – 7.5 ml
21 - 30 kg	3 x 7.5 - 10 ml
31 - 40 kg	3 x 10 - 15 ml
41 - 50 kg	3 x 15 - 17.5 ml

Method of administration

The syrup is taken orally using the measuring spoon provided in the package. To facilitate dosing, the measuring spoon is divided into 1.25 ml, 2.5 ml and 5 ml.

One full measuring spoon (5 ml) of syrup contains 250 mg of the drug.

If you use more Inosipranol syrup than you should

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

If you forget to use Inosipranol syrup

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 using Inosipranol syrup

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, pharmacist or nurse.

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.: +35 928903417
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 syrup

Keep out of reach of children.

Store below 25 °C

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

Shelf life after first opening the bottle - 6 months.

Do not throw away any medicines 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 Inosipranol syrup contains

- The active substance is inosine pranobex. 1 ml of syrup contains 50 mg of inosine pranobex.
- The other ingredients are: sucrose, methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium citrate, peach flavor, purified water.

What Inosipranol syrup looks like and contents of the pack

Clear, colorless to pale yellow liquid with peach aroma.

100 ml, 140 ml and 150 ml syrup in dark glass bottles closed with "child-resistant" plastic screw caps and a protective ring.

1 (one) bottle, with a measuring spoon with divisions of 1.25 ml, 2.5 ml and 5 ml, together with a patient leaflet is packed in a cardboard box.

Marketing Authorisation Holder

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