

Package leaflet: Information for the user

Viruxan® Forte 1000 mg powder for oral solution

Inosine Acedoben Dimepranol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Always take this medicine exactly as described in this leaflet or as your pharmacist have told you.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

1. What Viruxan® Forte 1000 mg powder for oral solution is and what it is used for
2. What you need to know before you take Viruxan® Forte 1000 mg powder for oral solution
3. How to take Viruxan® Forte 1000 mg powder for oral solution
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1. What Viruxan® Forte 1000 mg powder for oral solution is and what it is used for

This is a medicine which could be add in immunocompetent adolescents and adults as non-specific immunomodulatory agent to standard treatment of upper viral respiratory tract infections (e.g. acute rhinopharyngitis, acute pharyngitis, acute laryngitis, acute laryngopharyngitis).

2. What you need to know before you take Viruxan® Forte 1000 mg powder for oral solution

Do not take Viruxan® Forte 1000 mg powder for oral solution

- if you are allergic to inosine acedoben dimepranol or any of the other ingredients of this medicine (listed in section 6);
- if you have acute attack caused by gout;
- in case of pathologic increase in serum uric acid (it can be detected with laboratory test).

Warnings and precautions

Talk to your doctor or pharmacist before taking Viruxan® Forte 1000 mg powder for oral solution

- if you have any renal or urolithic diseases;
- if you suffer from any other diseases;
- if you had previously gout, elevated uric acid blood level, kidney stone or impaired renal function.
- if you notice signs of allergic reaction such as rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue. In such case you should stop the treatment immediately and visit your doctor.

In all these cases please inform your doctor before start of the treatment with Viruxan® Forte.

Other medicines and Viruxan® Forte 1000 mg powder for oral solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It can be used together with other medicine by physician's order, because in this case the effect of the medicines can be modified.

Especially tell your doctor or pharmacist if you are taking any the following medicines:

- drugs that modify the operation of the immune system
- uric acid formation inhibitors or uric acid excretion inducers
- diuretics
- zidovudin (medicine for HIV infection treatment)

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant you should not take Viruxan® Forte. If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Viruxan® Forte has no or negligible influence on the ability to drive and use machines.

3. How to take Viruxan® Forte 1000 mg powder for oral solution

Always take this medicine exactly as described in this leaflet or as pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Viruxan® Forte is intended exclusively for oral administration.

- Open the sachets just directly before use. The opened sachet should be disposed of in accordance with local requirements on medicinal products if not used immediately.
- The content of the sachet, Viruxan® Forte powder should be dissolved in one glass or at least 100 ml of water, either cold or at room temperature, immediately before taking the medicine.
For better dissolution of the content, stir the water.
- Do not make it in advance. When the powder is dissolved, do not store the medicine for future use. Discard, if not taken immediately.

You can take this medicine with or without food, equally divided doses during the day.

The recommended dose of the product

For adults and the elderly:

50 mg/kg b.w. daily, administered orally in 3 – 4 equally divided doses during the day. Usually 3 g/day (1 sachet 3 times a day) up to a maximum of 4 g/day (1 sachet 4 times a day).

Children and adolescents with body weight \geq 60 kg

the recommended dose is 50 mg/kg b.w. daily, usually 3 g/day up to a maximum of 4 g/day (usually 1 sachet 3 – 4 times a day).

The daily dose of 4 g should not be exceeded. Viruxan® Forte should not be taken for longer than 7 days without a consultation with a physician.

If you take more Viruxan® Forte 1000 mg powder for oral solution than you should

There have been no cases of overdose reported to date. If you have taken more sachets than you should, please contact your doctor.

If you forget to take Viruxan® Forte 1000 mg powder for oral solution

If you forget to take Viruxan® Forte just continue in the normal dosage as mentioned in this leaflet. Do not take a double dose to make up for a forgotten dose.

If you stop taking Viruxan® Forte 1000 mg powder for oral solution

If you interrupt or prematurely discontinue the treatment you should be aware that the desired effect could not be achieved or the symptoms may worsen again. Consult your doctor before stopping the 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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Tell your doctor immediately if you get:

- any sudden wheeziness,
- difficulty in breathing,
- swelling of the eyelids, face or lips,
- rash or itching (especially affecting your whole body).

The following side effects have been reported:

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

- temporary raised blood and urine uric acid level, but this will normalize some days after closing the treatment.

Common (may affect up to 1 in 10 patients):

- headache, dizziness,
- nausea, vomiting, stomach ache/discomfort,
- skin rash, itching,
- joint pain,
- tiredness (fatigue) or weakness (malaise),
- increased liver enzymes, blood urea increased

Uncommon (may affect up to 1 in 100 patients):

- nervousness,
- troubled sleep (somnolence, insomnia),
- diarrhoea, constipation,
- increased urinary volume.

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

- swelling of the face, lips, eyelids or throat (angioedema), hives, allergic reaction, whole-body allergic reaction (anaphylactic reaction),
- dizziness,
- gastric and abdominal pain,
- skin redness (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 the national reporting system listed in Appendix V.* By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Viruxan® Forte 1000 mg powder for oral solution

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

No special storage conditions are required.

The medicine should be taken immediately after dissolution.

Do not use this medicine after the expiry date (Expiry date/Exp:) which is stated on outer carton and on the sachet. 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 Viruxan® Forte 1000 mg powder for oral solution contains

- The active substance is inosine acedoben dimepranol. Each sachet contains 1000 mg inosine acedoben dimepranol.
- Excipients: mannitol (E421), sucralose, povidone K30, purified water, lemon flavour.

What Viruxan® Forte 1000 mg powder for oral solution looks like and contents of the pack

White to off-white free flowing powder with citrus smell, completely soluble in water.

Viruxan® Forte 1000 mg powder for oral solution is available in the carton box with 24 or 12 sachets.

Marketing Authorization Holder

Ewopharma International, s.r.o.
Prokopa Velkého 52
811 04 Bratislava, Slovak Republic

Manufacturer:

Lusomedicamenta – Sociedade Técnica Farmaceutica, S.A.
Queluz de Baixo, Barcarena
Portugal

This leaflet was last revised in January 2022.



Please adapt this PIL according to the text approved by national competent authority in your country.