

Package leaflet: Information for the user

Viruxan® Kids 50 mg/ml syrup 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 has 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.

The name of your medicine is Viruxan® Kids 50 mg/ml syrup, which will be called Viruxan® Kids or Viruxan® Kids syrup throughout this leaflet.

What is in this leaflet:

1. What Viruxan® Kids syrup is and what it is used for
2. What do you need to know before you take Viruxan® Kids syrup
3. How to take Viruxan® Kids syrup
4. Possible side effects
5. How to store Viruxan® Kids syrup
6. Contents of the pack and further information

1. What Viruxan® Kids syrup is and what it is used for

This is a medicine which could be added 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® Kids syrup

Do not take Viruxan® Kids syrup:

- If you are allergic (hypersensitive) to inosine acedoben dimepranol or any of the other ingredients of this medicine (listed in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- If you are suffering from gout or have been told that you have raised uric acid levels.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Viruxan® Kids syrup.

Take special care with Viruxan® Kids syrup and tell your doctor:

- If you have a history of gout or raised uric acid levels
- If you have a history of kidney stones
- If you have a kidney disorder (you will need to be monitored)
- If you are having long-term treatment, you will need regular blood tests and have your kidney and liver function checked. In patients receiving a long-term therapy, kidney stones are possible
- 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.

Other medicines and Viruxan® Kids syrup

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. Especially tell your doctor if you are taking the following medicines, as they may react with Viruxan® Kids syrup:

- Allopurinol or other treatments for gout
- Diuretics (medicines used to remove water from the body)
- Drugs used to suppress the immune system, e.g., after an organ transplant
- Zidovudine (azidothymidine) a treatment for AIDS.

It may still be all right for you to be given Viruxan® Kids syrup and your doctor will be able to decide what is suitable for you.

Pregnancy and 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.

Do not take Viruxan® Kids syrup if you are pregnant or breast-feeding unless your doctor tells you to do.

Driving and using machines

Viruxan® Kids syrup is unlikely to interfere with your ability to drive or use machines.

Viruxan® Kids syrup contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, sucrose and ethanol.

Viruxan® Kids syrup contains methyl parahydroxybenzoate and propyl parahydroxybenzoate that may cause allergic reactions (possibly delayed).

Viruxan® Kids syrup contains sucrose. 1 ml of syrup contains 650 mg of sugar (sucrose). This should be taken into account 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.

This medicinal product contains sodium. One single dose of Viruxan® Kids syrup exceeding 10 ml contains more than 1 mmol of sodium. This should be taken into consideration by patients on a controlled sodium diet.

This medicinal product contains small amount of ethanol (alcohol), less than 100 mg per dose.

3. How to use Viruxan® Kids syrup

Always take Viruxan® Kids syrup exactly as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Viruxan® Kids is intended exclusively for oral administration. The dose depends on your lean body weight and how severe your condition is. The daily dose is divided evenly during waking hours.

The recommended dose of the product

For adults and the elderly:

The recommended dose is 50 mg/kg b.w. daily (1 ml/kg), administered orally in 3–4 equally divided doses during the day. One measuring spoon (5 ml) of syrup contains 250 mg of Viruxan® Kids

Children over the age of 1 year:

The recommended dose is 50 mg/kg b.w. daily (1 ml/kg), administered orally in 3–4 equally divided doses during the day or according to the table below:

Body Weight	Daily dosage
10 – 14 kg	3 × 5 ml
15 – 20 kg	3 × 5 – 7,5 ml
21 – 30 kg	3 × 7,5 – 10 ml
31 – 40 kg	3 × 10 – 15 ml
41 – 50 kg	3 × 15 – 17,5 ml

The length of treatment depends on your response to treatment.

The daily dose of 4 g should not be exceeded.

Viruxan® Kids should not be taken for longer than 7 days without a consultation with a physician.

If you take more Viruxan® Kids syrup than you should

There have been no cases of overdose reported to date. If you are not sure or if you feel unwell, contact your doctor as soon as possible.

If you forget to take a dose of Viruxan® Kids syrup

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

If you stop using Viruxan® Kids syrup

If you stop the treatment the desired effect may 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 product ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects described below have been experienced by people taking Viruxan® Kids and they are listed as either very common, common, or uncommon.

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 people):

- Temporary raised blood and urine uric acid level.

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

- Increased liver enzymes, blood urea increased (a waste product),
- Skin rash, itching,
- Joint pain,
- Vomiting, feeling sick (nausea), stomachache,
- Tiredness (fatigue), weakness (malaise),
- Headache, spinning sensation (vertigo).

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

- Diarrhoea, constipation,
- Sleepiness (somnolence), not being able to sleep (insomnia),
- Nervousness,
- Increased urinary volume (polyuria).

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

- Abdominal pain,
- Swelling of the face, lips, eyelids or throat (angioedema), hives, allergic reaction, whole-body allergic reaction (anaphylactic reaction),
- Impairment of stability (dizziness),
- Skin redness (erythema)

Reporting of suspected adverse reactions

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® Kids syrup

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

Store below 25 °C.

Do not use Viruxan® Kids syrup longer than 6 months after first opening.

Do not use after the expiry date which is stated on the carton. 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 to protect the environment.

6. Contents of the pack and other information

What Viruxan® Kids syrup contains

- The active substance is inosine acedoben dimepranol. 1 ml syrup contains 50 mg inosine acedoben dimepranol. One measuring spoon (5 ml) of syrup contains 250 mg of inosine acedoben dimepranol.
- Excipients: sucrose, methylparahydroxybenzoate, propylparahydroxybenzoate, sodium hydroxide, plum flavour, purified water, sodium-dihydrogen citrate.

What Viruxan® Kids syrup looks like and contents of the pack

Clear, almost colourless syrup with a fruity plum odor. Viruxan® Kids syrup comes in 150ml amber glass bottles packed in carton box with a patient information leaflet and dosing spoon.

Marketing Authorisation Holder

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This leaflet was last approved in January 2022.



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