Package Leaflet: Information for the user

FERVEX, granules for oral solution in sachet (for adults)
paracetamol, pheniramine maleate, ascorbic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- 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 5 days.

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

1. What Fervex is and what it is used for

Fervex is used for simultaneous reduction of fever, pain relief and symptomatic treatment of rhinitis in adults and children over 15 years. Fervex consists of three active substances:
- paracetamol, relieving pain and reducing fever;
- anti-allergic substance pheniramine maleate, reducing nasal discharge, nasal congestion, tear flow and sneezing;
- vitamin C (ascorbic acid), reducing the body’s increased requirement for it during fever and colds.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you use Fervex

Do not take Fervex
- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from a severe liver disease;
- if you have glaucoma (a disease of increased intraocular pressure);
- if you have difficulty urinating (due to an enlarged prostate or other prostate problems);
- age under 15 years;
- if you use concomitant monoamine oxidase (MAO) inhibitor and up to 2 weeks after stopping treatment with MAO inhibitor;
- if you are pregnant or breast-feeding.

Check with your doctor, pharmacist or nurse if you are not sure.

Warnings and precautions

In case of overdose or accidentally taking a large amount of medicine, consult your doctor immediately. This medicine contains paracetamol. Do not take simultaneously with other drugs containing paracetamol, including over-the-counter drugs, in order not to exceed the
maximum daily doses allowed (see Dosage section). Consult your doctor or pharmacist before taking medicines containing paracetamol.

Talk to your doctor if you develop purulent nosebleeds, persistent fever, or pain that lasts longer than 3 days, or if you do not feel better after 5 days.

Ask your doctor or pharmacist for advice before using Fervex:
- if you are an adult and your body weight is less than 50 kg,
- if you are taking other medicines containing paracetamol (including medicines obtained without a prescription).
- if you have kidney or liver disease,
- in case of chronic alcoholism,
- if you have a nutritional disorder (malnutrition, low glutathione in the liver) or dehydration
- if you have or have been diagnosed with acute viral hepatitis while taking Fervex, talk to your doctor. The doctor may decide to stop treatment.

Vitamin C should be used with caution in patients diagnosed with glucose-6-phosphate dehydrogenase deficiency (risk of hemolytic anemia) and iron metabolism disorders;

Paracetamol can cause serious skin reactions. If you develop a skin rash or other allergy symptoms, stop treatment and seek medical attention immediately.

Children and adolescents
When treating children with paracetamol, other antipyretic drugs can be used simultaneously only if the drug is ineffective and under strict medical supervision.

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

If you are taking medicine that reduces blood clotting (oral anticoagulants), contact your doctor. At high doses, Fervex can increase the effect of this medicine. If necessary, your doctor will adjust the dose of your medicine.
If you or your child are being tested for blood uric acid or sugar levels, tell the doctor that you or your child are taking this medicine.

To avoid an overdose, check that other medicines administered at the same time do not contain antihistamines (allergy medicines) or paracetamol, unless prescribed by a doctor.

Caution should be exercised when administering paracetamol simultaneously with flucloxacillin, as the development of metabolic acidosis with high anion gaps has been observed, especially in patients with concomitant risk factors.

Pregnancy and breast-feeding
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.

If necessary, Fervex can be used during pregnancy. Use the lowest possible dose that reduces pain and/or fever for the shortest possible time. If the pain and/or fever does not go down or you need to use the medicine more often, contact your doctor or midwife.

Because there are no data from animal studies and clinical studies, the use of this medicine is contraindicated during pregnancy and breast-feeding.

Driving and using machines
Do not drive or use machines during treatment as the use of this medicine may be accompanied by day-time sleepiness.
Fervex contains sugar, alcohol and sodium
This medicine contains 11.6 g of sucrose per dose. This must be taken into account in patients with diabetes. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains small amounts (7 mg) of alcohol (ethanol), less than 100 mg per sachet.

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially ‘sodium-free’.

3. How to take Fervex

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

Dosage

<table>
<thead>
<tr>
<th>Age (body weight)</th>
<th>Single dose</th>
<th>Dosing interval</th>
<th>Maximum daily dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and adolescents over 15 years of age (with body weight over 50 kg)</td>
<td>1 sachet (500 mg paracetamol, 25 mg pheniramine, 200 mg ascorbic acid)</td>
<td>At least 4 hours</td>
<td>3 sachets (1500 mg paracetamol, 75 mg pheniramine, 600 mg ascorbic acid)</td>
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The maximum daily dose of paracetamol should not exceed 3000 mg, as it can cause serious damage to the liver.

To avoid overdose, check that other concomitant medications do not contain paracetamol and/or pheniramine and/or ascorbic acid, including over-the-counter medications.

Patients with kidney or liver impairment
Consult your doctor or pharmacist before using the medicine.
In case of renal failure, there should be an interval of at least 8 hours between two administrations.

The usual dose is 1 sachet 2...3 times a day. There should be at least 4-hour interval between two administrations.

Method of administration
Pour the contents of a sachet into a glass, pour on hot or cold water and mix until dissolution. Drink the solution immediately.
The maximum duration of treatment is 5 days.

If you have the impression that the effect of Fervex is too strong or too weak, talk to your doctor or pharmacist.

If you take more Fervex than you should
If you take more Fervex than you should, tell your doctor or pharmacist immediately.
Overdosage of paracetamol in large amounts causes severe liver damage. The early signs of poisoning appear usually during 24 hours (nausea, vomiting, loss of appetite, general malaise, consciousness disorders). If severe poisoning is suspected, contact a hospital immediately.

If you forget to take Fervex
Do not take a double dose to make up for a forgotten dose.
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.

**Paracetamol related side effects**
In some rare cases, there have been skin rashes (redness of the skin, hives, itching) and/or allergic reactions, which manifest themselves as sudden swelling of the face or neck or a drop in blood pressure. In this case, treatment with paracetamol should be stopped immediately and a doctor should be consulted.

Rarely, there have been some cases of neutropenia, leukopenia or thrombocytopenia (a low number of blood cells that are important in fighting infections or blood clotting).

**Side effects associated with pheniramine**
- persons with a predisposition to the development of acute glaucoma,
- urination disorders (significantly reduced urine volume, urination difficulties),
- dry mouth, visual disturbances, constipation,
- concentration or memory disorders, confusion, dizziness (more common in the elderly),
- coordination disorders, tremors,
- drowsiness, decreased alertness, which occurs more at the beginning of treatment,
- drop in blood pressure when standing up, which may be accompanied by dizziness.

If you get any of these side effects, stop using this medicine at once and contact a doctor.

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

5. **How to store Fervex**

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the package. 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 Fervex contains**
- The active substances are paracetamol, pheniramine maleate and ascorbic acid (vitamin C). In one sachet the granules contain paracetamol 500 mg, pheniramine maleate 25 mg and ascorbic acid (vitamin C) 200 mg.
- The other excipients are gummi arabicum, anhydrous citric acid, saccharin sodium and natural West Indies aroma, containing maltodextrin (a source of glucose and fructose) and small amounts of ethanol and sodium.

**What Fervex looks like and contents of the pack**
Granules for oral solution in sachets (paper-aluminium-polyethylene). Sachets are packaged in boxes. There are 8 sachets in a box.
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
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