Package Leaflet: Information for the user

FERVEX, granules for oral solution in sachet (for children)
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 use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has 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 effect, talk to your doctor, pharmacist or nurse. 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 3 days.

What is in this leaflet
1. What Fervex is and what it is used for
2. What you need to know before you use Fervex
3. How to use 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 the simultaneous reduction of fever, pain relief and symptomatic treatment of rhinitis in children over the age of 6. Fervex contains three active ingredients:
- paracetamol, which relieves pain and reduces fever;
- pheniramine maleate, an anti-allergy agent which reduces nasal discharge, nasal congestion, teary eyes and sneezing;
- vitamin C (ascorbic acid), to fulfil the organism’s increased need thereof caused by fever and the cold.

You must contact a doctor if you do not feel better or if you feel worse after 3 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 ingredients of this medicine (listed in paragraph 6);
- if you have severe liver disease
- if you have glaucoma (increased intraocular pressure);
- if you have difficulty urinating (due to an enlarged prostate or other prostate problems);
- under the age of 6 years;
- if you are concurrently being treated with a monoamine oxydase (MAO) inhibitor and up to 2 weeks after discontinuation of treatment with the MAO inhibitor
- if you are pregnant or breast-feeding

Check with your doctor or pharmacist 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 more than 3 days, or if you do not feel better after 3 days.

Talk to your doctor or pharmacist before taking Fervex:
- if you are taking other medicines containing paracetamol (including medicines obtained without a prescription),
- if you have kidney or liver disease,
- 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 symptom, **stop treatment and seek medical attention immediately**.

**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 you take 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, 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 using 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.

Due to the lack of data from animal experiments and clinical studies, the use of this drug during breastfeeding is contraindicated.

**Driving and using machines**

Do not drive or use machines during treatment, as the use of this medicine may cause daytime sleepiness.
Fervex contains dyes sunset yellow FCF (E110) and magic red AC (E129) and a small amount of benzyl alcohol and sodium benzoate (E202)
Sunset Yellow FCF (E110) and Magic Red AC (E129) may cause allergic reactions.

This medicine contains 0.28 mg of benzyl alcohol in a sachet. Benzyl alcohol can cause allergic reactions. Consult your doctor or pharmacist if you are pregnant or breastfeeding. Benzyl alcohol taken in large amounts can build up in your body and cause side effects (called 'metabolic acidosis'). Consult your doctor or pharmacist if you have liver or kidney disease.

This medicine contains 0.0036 mg of sodium benzoate (E202) in a sachet.

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

3. How to use Fervex

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

Dosage

<table>
<thead>
<tr>
<th>Age and body weight</th>
<th>Single dose</th>
<th>Dosing interval</th>
<th>Maximum daily dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>21…25 kg (approximately 6 to 10 years old)</td>
<td>1 sachet (280 mg of paracetamol, 10 mg of pheniramine, 100 mg of ascorbic acid)</td>
<td>12 hours</td>
<td>2 sachets (560 mg of paracetamol, 20 mg of pheniramine, 200 mg of ascorbic acid)</td>
</tr>
<tr>
<td>26…40 kg (approximately 10…12 years old)</td>
<td>1 sachet (280 mg of paracetamol, 10 mg of pheniramine, 100 mg of ascorbic acid)</td>
<td>8 hours</td>
<td>3 sachets (840 mg of paracetamol, 30 mg of pheniramine, 300 mg of ascorbic acid)</td>
</tr>
<tr>
<td>41…50 kg (approximately 12…15 years old)</td>
<td>1 sachet (280 mg of paracetamol, 10 mg of pheniramine, 100 mg of ascorbic acid)</td>
<td>6 hours</td>
<td>4 sachets (1120 mg of paracetamol, 40 mg of pheniramine, 400 mg of ascorbic acid)</td>
</tr>
</tbody>
</table>

The maximum daily dose of paracetamol should not exceed 60 mg/kg.

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

Kidney or liver damage, Gilbert's syndrome (familial non-haemolytic jaundice)
Consult your doctor or pharmacist before using this medicine.

In case of renal failure, there should be an interval of at least 8 hours between two administrations.

Method of administration
Pour the contents of the sachet into a glass, add hot or cold water and stir until dissolved. Drink the solution at once.
The maximum duration of treatment is 3 days.

Talk to your doctor or pharmacist if you feel that the effect of Fervex is too strong or too weak.
If you take more Fervex than you should
If you or your child take more Fervex than recommended, tell your doctor or pharmacist at once. Large overdoses of paracetamol can cause severe liver damage. The early signs of intoxication usually appear within 24 hours (nausea, vomiting, inappetence, general malaise, mentation disorders). If you suspect severe intoxication, go to the hospital at once.

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.

Side effects associated with paracetamol
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
- development of acute glaucoma in persons with a predisposition,
- 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.

Reporting of side effects
If you get any side effects, as advice from your doctor, pharmacist or nurse. 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 pack and sachets. 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 ingredients are paracetamol, pheniramine maleate and ascorbic acid (vitamin C). One sachet of granules contains 280 mg of paracetamol, 10 mg of pheniramine maleate and 100 mg of ascorbic acid (vitamin C).
- The other ingredients are mannitol (E421), anhydrous citric acid (E330), povidone, anhydrous magnesium citrate, potassium acesulfame (E950), sodium benzoate (E202), raspberry flavoring containing sunset yellow FCF (E110) and magic red AC (E129), benzyl alcohol, ethanol.

What Fervex looks like and contents of the pack
Granules for oral solution in sachets (paper-aluminium-polyethylene). One cardboard box contains 8 sachets.

Marketing Authorisation Holder
UPSA SAS
3, rue Joseph Monier
92500 Rueil-Malmaison
France

Manufacturer
UPSA SAS
304 avenue du Docteur Jean Bru
47000 Agen
France

UPSA SAS
979 Avenue des Pyrénées
47520 Le Passage
France

For any information about this medicine, please contact the representative of the Marketing Authorisation Holder.
Swixx Biopharma
phone: 640 1030
e-mail: medinfo.estonia@swixxbiopharma.com

This leaflet was last revised in April 2022.