

Package leaflet: Information for the patient

Gripoff granules for oral solution in sachet

Paracetamol/ Ascorbic acid / Chlorphenamine maleate

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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, 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 5 days.

What is in this leaflet

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

1. What Gripoff is and what it is used for

Gripoff belongs to the group of medicines called analgesics - antipyretics.

Therapeutic indications

Gripoff is a medicine used against cold and flu, which contains three active ingredients:

- paracetamol which relieves pain and reduces fever;
- chlorphenamine maleate reduces nasal congestion, watery eyes, often associated with cold and flu, and acts on phenomena like sneezing;
- vitamin C (ascorbic acid) helps to replace Vitamin C lost in the early stages of cold and flu.

Gripoff is a remedy used in the short-term for symptomatic relief of flu, fever, chills and common cold, including headache, sore throat, discomfort and pain, nasal congestion, sinusitis, as well as the pain and acute nasal catarrh, associated with it.

This medicine is intended for use by adults and adolescents older than 15 years of age.

Treatment with antibiotics may be necessary in case of bacterial infections.

2. What you need to know before you take Gripoff

Do not take Gripoff:

- if you are allergic to paracetamol, phenacetin or other anti-inflammatory drugs, pheniramine or other antihistamines or any other ingredients of this medicine (listed on section 6);
- if you have a glucose-6-phosphate dehydrogenase deficiency;
- if you are suffering from severe kidney disease (the risk of side effects on the kidneys may be increased with prolonged administration of high doses);
- if you have urethroprostatic disorders with risk of urinary retention;
- if you are suffering from closed angle glaucoma, a family history of closed angle glaucoma or open angle glaucoma;
- if you are suffering from severe liver disease;
- if you are in concomitant treatment with non-selective monoamine oxidase inhibitors (MAOIs);
- if you are suffering from kidney stones (high doses - 1 g of ascorbic acid for long periods of time);
- if you have intolerance to some categories of sugars (contains sugar);
- if you are under 15 years of age.

Warnings and precautions

Before using Gripoff, talk to your doctor, pharmacist or nurse.

Do not exceed the indicated doses and consult a doctor if this happened accidentally.

If allergic reactions occur, the treatment will be stopped immediately.

Do not combine Gripoff with other medicines (for example: barbiturates, carbamazepine, hydantoin, rifampicin, sulfinpyrazone, combined estrogen-progesteron contraceptives, antifungals, doxorubicin, isoniazid, mercaptopurine, methotrexate, gold salts, barbiturates, primidone, coumarin anticoagulants, non-steroidal anti-inflammatory drugs, cyclosporine, morphine agonists, antacids, activated charcoal, anticholinergics, phenicols, sultopride, MAOIs, CNS depressants, atropine, phenytoin, deferoxamine) without consulting with your doctor or pharmacist. To avoid potential interactions between different medicines, you must inform your doctor or pharmacist if you have taken or are currently taking other medicines.

Do not use Gripoff if you suffer from kidney disease, without having an approval from the doctor.

Keep Gripoff out of the reach and sight of children.

Due to the sugar content, special care must be taken with this medicine in case of diabetes, fructose intolerance, glucose or galactose malabsorption or sucrase-isomaltase deficiency (a rare genetic disease).

Caution is required when administering to the elderly people.

Please ask your doctor if you are or have ever been in one of these situations.

Other medicines and Gripoff

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

Do not use Gripoff at the same time as another medicine containing paracetamol. Do not combine Gripoff with other medicines (for example: barbiturates, carbamazepine, hydantoin, rifampicin, sulfinpyrazone, combined estrogen-progesteron contraceptives, antifungals, doxorubicin, isoniazid, mercaptopurine, methotrexate, gold salts, barbiturates, primidone, coumarin anticoagulants, non-steroidal anti-inflammatory drugs, cyclosporine, morphine agonists, antacids, activated charcoal, anticholinergics, phenicols, sultopride, MAOIs, CNS depressants, atropine, phenytoin, deferoxamine) without consulting with your doctor or pharmacist.

To avoid potential interactions between different medicines, you must inform your doctor or your pharmacist if you have taken or are currently taking other medicines. If you are going to have any laboratory investigations, tell the doctor that you are taking Gripoff.

Gripoff with food, drink and alcohol

Do not consume alcohol, medicines or food containing alcohol during treatment with Gripoff.

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.

Pregnancy

Ask your doctor or your pharmacist before using any medicine.

Tell your doctor if you are pregnant or are planning to have a baby.

Due to the absence of animal and human studies, the risk is unknown. Consequently, as a precautionary measure, this medicine should not be administered during pregnancy or breast-feeding.

Breast-feeding

Ask your doctor or your pharmacist before using any medicine during breast-feeding.

Driving and using machines

Due to its side effects (as an example, sleepiness, drowsiness, state of confusion, dizziness, visual accommodation disorders etc.), the product may influence your ability to drive vehicles and operate machinery.

Gripoff contains sugar

This should be taken in consideration in patients with diabetes.

If your doctor ever mentioned that you have intolerance to some types of sugars, please ask them before using this medicine.

3. How to take Gripoff

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

Adults and adolescents (over the age of 15):

1 sachet of Gripoff 2-3 times a day. The interval between administrations must be at least 4 hours.

If you suffer from severe kidney damage, the interval between administrations must be at least 8 hours.

The content of one sachet of Gripoff is dissolved in a cup of hot water (approximately 200 ml). A lemon-flavored drink is obtained which is drunk hot. Do not dissolve and do not administer more than one sachet once.

For the treatment of flu-like symptoms, it is preferable to administer this medicine with hot water in the evening, from the moment the first symptoms.

Inform your doctor or pharmacist if the discomfort persists even after 5 days of treatment. Your doctor will inform you how long the treatment with Gripoff will last.

If you have the impression that the effect of Gripoff is too strong or too weak, ask your doctor or pharmacist.

If you take more Gripoff than you should

Seek medical advice immediately and explain exactly how much you have taken. Your doctor will advise you what to do.

It is important to tell your doctor, even if you feel well. If a person has taken too much paracetamol, there is a serious risk of liver damage level due to the delay in treatment initiation.

If you forget to use Gripoff

Do not take a double dose to compensate the forgotten dose.

Take the next dose as soon as you remember and continue treatment.

If you have any further questions about this medicine, ask to your doctor, pharmacist or nurse.

4. Possible side effects

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

The adverse reactions are classified according to their frequency, using the following convention:

Very common	may affect more than 1 in 10 people
Common	may affect up to 1 in 10 people
Uncommon	may affect up to 1 in 100 people
Rare	may affect up to 1 in 1000 people
Very rare	may affect up to 1 in 10000 people
Not known	frequency cannot be estimated from the available data

Very rare side effects:

Associated with paracetamol:

- decrease in the number of a type of blood cells called platelets (thrombocytopenia);
- transitory skin rashes and other allergies, including a sudden severe allergic reaction involving the whole body called anaphylaxis;
- narrowing of the airways due to muscle spasm (bronchospasm);
- liver disorders.

Associated with ascorbic acid:

- digestive disorders: diarrhea, burning in the upper part of the abdomen, (heartburn);
- kidney disorders: "kidney stones" (renal and uric lithiasis)

Side effects with unknown frequency:

Associated with chlorphenamine maleate:

- increase in blood pressure;
- headaches;
- dizziness;
- inability to sleep (insomnia);
- disturbing perception of the heartbeat (palpitations).

These reactions should disappear if you stop taking Gripoff.

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, of which details are published on the website of the National Agency for Medicines and Medical Devices (<http://www.anm.ro>). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gripoff

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

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

Store below 25°C, in the original package.

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 Gripoff contain

Active ingredients are paracetamol, ascorbic acid and chlorphenamine maleate.

One sachet with granules for oral solution contains paracetamol 500 mg, ascorbic acid 200 mg, chlorphenamine maleate 4 mg.

Other ingredients are: anhydrous citric acid, sodium saccharine, sugar, lemon flavor.

How Gripoff looks like and contents of the pack

Gripoff is in the form of homogeneous white-yellowish granules, with a faint characteristic lemon smell.

Box with 6 sachets of 13.1 g granules for oral solution.

Box with 8 sachets of 13.1 g granules for oral solution.

Marketing Authorization Holder and Manufacturer

S.C. Slavia Pharm S.R.L.

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This leaflet was last revised in April 2019.

Detailed information on this medicine is available on the website of the National Medicines and Medical Devices Agency <http://www.anm.ro/>