**Package leaflet: Information for the user**

# GRIPOFLEX 500
# powder for oral solution

Paracetamol / Ascorbic acid / Pheniramine maleate

**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 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 3 days.

**What is in this leaflet**


## 1. What Gripoflex 500 is and what it is used for

Gripoflex 500 belongs to a group of combined analgesic (pain relieving) and antipyretic (fever reducing) medicines. It contains three active substances: paracetamol, ascorbic acid (vitamin C) and pheniramine maleate (further in the text referred to as pheniramine).
Gripoflex 500 is used to relieve the symptoms of flu, cold and upper respiratory tract inflammation including headache, aches and pains, fever, nasal and sinus congestion (nasal stuffiness), rhinitis (runny nose) and sneezing.

## 2. What you need to know before you use Gripoflex 500

**Do not use Gripoflex 500**
- if you are allergic to active substances or any of the other ingredients of this medicine (listed in section 6);
- if you have high blood pressure (arterial hypertension);
- if you have closed angle glaucoma;
- if you have severe liver, kidney, cardiovascular, thyroid gland, lung problems (including bronchial asthma);
- if you have stomach or duodenal ulcer;
- if you have pancreas or urinary bladder diseases;
- if you have difficulties in urinating (in case of prostatic adenoma);
- if you have blood-forming disorders;

- if you have a rare hereditary condition called glucose-6 phosphate dehydrogenase deficiency (abnormality of red blood cells);
- if you are pregnant or breast-feeding.

This medicine should not be taken by children and adolescents below 15 years of age.

It is not recommended for use in patients with increased coagulation activity.

Gripoflex 500 should not be used together with other medicines containing paracetamol and/or pheniramine maleate, non-steroidal anti-inflammatory drugs (NSAIDs), medicines affecting central nervous system (CNS) (hypnotics, tricyclic antidepressants, tranquilizers) medicines to treat high blood pressure.

**Warnings and precautions**
Stop taking Gripoflex 500 and contact your doctor **immediately** if you experience nausea, vomiting, abdominal pain, loss of appetite, malaise, dizziness, tinnitus (ringing in the ears), hearing impairment, excessive nervousness.

Talk to your doctor before taking Gripoflex 500 as particular caution is required in these cases:
- if you suffer from liver and/or kidney problems (in severe cases the use is prohibited);
- if you have blood-forming disorders;
- if you are over 65 years of age;
- if you are addicted to alcohol.

If fever and pain persist for more than 3 days or new symptoms, red or swollen throat appear, talk to your doctor.

Prolonged administration of large doses of paracetamol may cause toxic effects to the liver and kidneys.
Do not exceed the recommended doses!

**Other medicines and Gripoflex 500**
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Do not take together with NSAIDs, hypnotics, tricyclic antidepressants, tranquilizers, medicines to treat high blood pressure and medicines containing paracetamol and/or pheniramine.

Talk to your doctor or pharmacist if you take any of the following medicines:
- barbiturates, phenytoin, carbamazepine, rifampicin, hepatic microsomal enzyme inducers (increased risk for paracetamol induced liver damage);
- zidovudine (concomitant use with paracetamol may enhance toxicity of both medicines, a marked decrease in the number of granulocytes, a certain type of white blood cells, is observed more frequently);
- penicillin (ascorbic acid increases absorption of penicillin);
- heparin and anticoagulants of indirect action (ascorbic acid reduces efficacy of heparin and anticoagulants of indirect action);

- salicylates (ascorbic acid increases the risk of formation of crystals in urine if used together).

**Gripoflex 500 with alcohol**
Avoid alcoholic beverages whilst taking this medicine, as it may increase effects of alcohol. Alcohol may contribute also to development of undesirable side effects of paracetamol and/or acute pancreatitis.

**Pregnancy and breast-feeding**
The medicine must not be used during pregnancy and breast-feeding.

**Driving and using machines**
Do not drive or use potentially hazardous machines while on the treatment as this medicine contains may cause drowsiness and fatigue.

**This medicine contains aspartame and colorant sunset yellow FCF (E110)**
This medicine contains aspartame (a source of phenylalanine), which may be harmful for people with phenylketonuria.
This medicine contains colorant sunset yellow FCF (E110), which may cause allergic reactions.

## 3. How to use Gripoflex 500

Always take 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.

The treatment should be started as soon as possible following the first appearance of disease symptoms.

Dissolve the content of one sachet in a glass of hot water and drink whilst warm.

*Adults and adolescents 15 years of age and older*
One sachet to be taken three times a day and leave at intervals of not less than 4 hours between doses. Maximum daily dose is 3 sachets. Do not exceed the recommended doses.

*Patients with renal impairment*
The medicine should be taken at intervals of not less than 8 hours between doses.

*Elderly patients*
No dose adjustment is required.

**If you use more Gripoflex 500 than you should**
Paracetamol overdose could be dangerous. Seek immediate medical attention even if you feel well, because of the risk of delayed, serious overdose consequences.
*Symptoms:* nausea and vomiting, epigastric or abdominal pain, loss of appetite, dizziness, tinnitus (ringing in the ears), hearing impairment (especially in elderly patients), malaise.

**If you forget to use Gripoflex 500**
Do not take a double dose to make up for a forgotten dose.

## 4. Possible side effects

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

*Uncommon* (affects up to 1 user in 100)
- Dry mouth
- Nausea
- Epigastric pain
- Diarrhoea

*Rare* (affects up to 1 user in 1,000)
- Decreased response to stimuli, drowsiness, headache, confusion in elderly patients
- Accommodation disorders (impaired ability of the eye to focus)
- Increased heartrate
- Transient hypertension (high blood pressure)
- Rash, itching, hives, Quincke's oedema (sudden swelling of the face, lips, tongue, throat or other parts of the body, difficulties breathing and/or swallowing)
- Urination difficulty

*Very rare* (affects up to 1 user in 10,000)
- Anaemia (a deficiency of red blood cells)
- Thrombocytopenia (decreased number of platelets in the blood)
- Leucopoenia (decreased number of white blood cells)
- Agranulocytosis (significantly reduced number of granulocytes, a certain type of white blood cells, in the blood)
- Methemoglobinemia (a blood disorder in which an abnormal amount of methemoglobin, a form of hemoglobin, is produced)

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

## 5. How to store Gripoflex 500

Do not store above 25 °C. Protect from moisture.

Keep out of the sight and reach of children.

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 Gripoflex 500 contains**
Each sachet contains active substances:

| | |
|---|---|
| Paracetamol (*Paracetamolum*) | 500 mg |
| Ascorbic acid (*Acidum ascorbicum*) | 200 mg |
| Pheniramine maleate (*Pheniramini maleas*) | 25 mg |

The other ingredients (excipients) are aspartame, mannitol, flavour orange durarome, colorant sunset yellow FCF (E110).

**What Gripoflex 500 looks like and contents of the pack**
White with pink shade to pink powder. The presence of yellow and orange inclusions is allowed.

Sachets of laminated material (paper/polyethylene film/aluminium foil/polyethylene film) or sachets of laminated material (paper/polyethylene film/aluminium foil/ethylene and acrylic acid copolymer).

5 sachets of 5 g each are inserted together with the package leaflet in the carton box.

**Marketing Authorisation Holder and Manufacturer**
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