

Package leaflet: Information for the user

Gripoflex 500 Powder for Oral Solution

Paracetamol
Pheniramine maleate
Ascorbic acid

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

This medicine is available without prescription. However, you still need to use your medicine carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Gripoflex 500 is and what it is used for
2. What you need to know before you use Gripoflex 500
3. How to use Gripoflex 500
4. Possible side effects
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6. Contents of the pack and other information

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

Gripoflex 500 belongs to a group of combined analgesic (relieve pain) and antipyretic medicines (reduce fever). It contains 3 active substances: paracetamol, ascorbic acid (vitamin C) and pheniramine maleate (further in the text referred to as pheniramine).

It can be used to relieve the symptoms of cold, flu 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 small intestine (duodenal) ulcer.
- if you have pancreas and bladder diseases.
- if you are a man with prostate problems (prostatic adenoma leading to residual urine).

- if you have haematopoietic (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 breastfeeding.

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

It is not recommended for use, if you have increased coagulation activity.

Do not take with any other paracetamol and/or pheniramine maleate-containing products, non-steroidal anti-inflammatory and central nervous system (CNS) medicines (hypnotics, sedatives, tricyclic antidepressants) and antihypertensives (e.g. β blockers).

Warnings and precautions

Do not exceed the recommended dose!

Talk to your doctor, if your symptoms, such as fever and pain, persist for more than 3 days or new symptoms as red or swollen throat appear.

Take special care if you suffer from liver or kidney problems (in case of severe problems Gripoflex 500 is contraindicated), haematopoietic (blood-forming) disorders or if you are over 65 years of age.

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

Check with your doctor before using Gripoflex 500, if you have been drinking a lot of alcohol.

Other medicines and Gripoflex 500

Tell your doctor or pharmacist if you are taking, have recently used or might use any other medicines, including medicines obtained without a prescription.

- Do not take with any other paracetamol and/or pheniramine-containing products, non-steroidal anti-inflammatory and central nervous system (CNS) medicines (hypnotics, sedatives, tricyclic antidepressants) and antihypertensives (e.g. β blockers).
- Using Gripoflex 500 together with barbiturates, phenytoin, carbamazepine, rifampicin, hepatic microsomal enzyme inducers increases the risk of paracetamol-induced hepatotoxicity (liver damage).
- Concomitant use of zidovudine and paracetamol may enhance toxicity of both medicines, granulocytopenia (temporary shortage of white blood cells) is observed more frequently.
- Ascorbic acid increases absorption of penicillin, reduces efficacy of heparin and anticoagulants of indirect action, increases risk of crystalluria, if used together with salicylates.

If you have any further questions ask your doctor or pharmacist.

Gripoflex 500 with food and drink, and alcohol

Do not drink alcohol (e.g. wine, beer, spirits) whilst taking this medicine, it may increase effects of alcohol. Alcohol may induce possible side effects of paracetamol and/or acute pancreatitis development as well.

Pregnancy and breast-feeding

The use is contraindicated.

Driving and using machines

Whilst taking Gripoflex 500 do not drive or operate machinery. The medicine may cause drowsiness and fatigue.

Important information about some of the ingredients of your medicine

This medicine contains aspartame (a source of phenylalanine), which may be harmful for people with phenylketonuria.

This medicine contains colorant sunset yellow (E110), which may cause allergic reactions.

3. How to use Gripoflex 500

Treatment with Gripoflex 500 should be started as soon as possible after the first appearance of disease symptoms.

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

Adults and adolescents 15 years of age and older: take one sachet three times a day and leave at least 4 hours between each dose. In case of kidney disease Gripoflex 500 should be taken at intervals of not less than 8 hours.

Don't take more than 3 sachets in any 24-hour period!

If you take 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 are 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 take Gripoflex 500

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Gripoflex 500 can cause side effects, although not everybody gets them.

Side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000

Uncommon: dry mouth, epigastric pain, diarrhoea, nausea

Rare: slow response to stimuli, drowsiness, headache, confusion in elderly patients, accommodation disorders (impaired ability of the eye to focus), tachycardia (fast heart beat), transient hypertension (high blood pressure) rash, itching, urticaria, Quincke's oedema (allergic facial swelling), urination difficulty

Very rare: anaemia, leucopenia, thrombocytopenia, agranulocytosis, methemoglobinemia

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Gripoflex 500

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

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 package. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Gripoflex 500 contains

The active substances are paracetamol (Paracetamolium) 500 mg

ascorbic acid (Acidum ascorbicum) 200 mg

pheniramine maleate (Pheniramini maleas) 25 mg

The other 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.

Each carton pack contains 5 laminate sachets and a package leaflet.

Marketing Authorisation Holder and Manufacturer

JSC Olainfarm.

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This leaflet was last revised in 10.2017