

PACKAGE LEAFLET: Information for the patient

FLUGO

Film-coated tablets – 251 mg + 61.2 mg + 2.54 mg

(Paracetamol, Pseudoephedrine hydrochloride, Chlorpheniramine maleate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor, or pharmacist.
- This medication has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 FLUGO is and what it is used for
2. Before you take FLUGO
3. How to take FLUGO
4. Possible side effects
5. How to store FLUGO
6. Other information

1. WHAT FLUGO IS AND WHAT IT IS USED FOR

FLUGO film-coated tablets contain three active ingredients – paracetamol, pseudoephedrine hydrochloride and chlorpheniramine maleate, whose actions complement each other.

Paracetamol acts like an analgesic (relieves pain) and antipyretic (lowers body temperature). Pseudoephedrine hydrochloride narrows small blood vessels in the nasal mucosa, prevents excessive nasal secretions and relieves symptoms of nasal mucosal inflammation and sinuses.

Chlorpheniramine maleate, with its antihistaminic action, reduces nasal congestion, relieves symptoms of mucous membrane leakage and prevents eyes tearing.

FLUGO is used to relieve the symptoms of cold, flu or allergic rhinitis, such as:

- increased secretion from the nose;
- narrowing of the nose and sinuses;
- nose and eye rash;
- sensation of burning and tearing of the eyes;
- itching of the nose or throat;
- sneezing;
- headache;
- pain in the sinus area;
- sore throat;
- muscle and joint pain;
- increase of body temperature (fever);
- general weakness.

2. BEFORE YOU TAKE FLUGO

Do not take FLUGO if:

- you are sensitive (allergic) to the active substances and / or any of the excipients of this medicine (see section 6);
- you are currently taking MAO inhibitors (used to treat depression, psychiatric or emotional disorders and Parkinson's disease). FLUGO can be taken 14 days after stopping treatment with MAO inhibitors;
- you have severe liver damage;
- you have severe impairment of kidney function;
- you have severe heart disease, hypertension, diabetes, bronchial asthma, glaucoma, hyperthyroidism or epilepsy;
- if you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication;
- if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.

Take special care with FLUGO

You should not use other medicines containing paracetamol or medicines used to treat nasal congestion while taking FLUGO. Avoid consuming alcoholic beverages while taking FLUGO.

You should consult your doctor if you have:

- impaired liver / or kidney function;
- blockage of the bile ducts;
- obstruction (blockage) of the urinary bladder neck;
- hypertrophy (enlargement) of the prostate;
- pyloroduodenal obstruction (blockage in the upper part of the digestive tract);
- stomach or duodenal ulcer followed by stenosis (narrowing).

You should consult your doctor if you are taking antihypertensive medicines.

If you suddenly experience high temperature (fever) and rashes with small numerous pustules (like acne), stop taking FLUGO immediately and contact your doctor (see section 4).

If you don't feel better (fever lasts more than 3 days and nose congestion more than 7 days), you should consult your doctor.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using FluGo immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

One of the active ingredients in FluGo, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more FluGo than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 3).

Taking other medicines

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

Tell your doctor if you are taking one of the following medicines:

- Antidepressants (medicines for the treatment of depression – MAO inhibitors or tricyclic antidepressants);
- Propantheline (antimuscarinic drug, which slows stomach emptying);

- Metoclopramide and cisapride (drugs that accelerate stomach emptying);
- Phenytoin, carbamazepine and lamotrigine (medicines for the treatment of epilepsy);
- Sulfapyrazone (medicine used to treat cramping);
- Cholestyramine (a drug for lowering blood fat levels);
- Imatinib (medicine used to treat leukemia);
- Fenoldopam (heart medicine);
- Warfarin or other medicines to prevent blood coagulation;
- Dihydroergotamine (medicine for the treatment of migraines);
- Guanethidine (a drug used to treat high blood pressure);
- Medications that accelerate the heart rate (sympathomimetics, thyroid hormones, etc.);
- Barbiturates, benzodiazepines, hypnotics (painkillers), opioid analgesics and alcohol;
- Neuroleptics (medicines for the treatment of psychiatric disorders);
- Antibiotics (e.g. chloramphenicol, isoniazid);
- Zidovudine and lopinavir (medicines used to treat AIDS or HIV infection).

Taking FLUGO with food and drinks

You should not consume alcohol while using FLUGO.

Pregnancy

If you are pregnant or are planning to have a baby, tell your doctor before you take FLUGO.

There is no information on the safety of this drug during pregnancy, so it is usually not recommended. Your doctor will decide according to the risk / benefit balance.

Breastfeeding

If you are breastfeeding, tell your doctor before you take this medication.

Small amounts of some ingredients can pass into breast milk and can cause side effects to the baby, so do not breastfeed your baby while taking this medicine.

Driving and using machines

FLUGO can cause drowsiness, so it reduces psychophysical abilities. If this happens to you, you should not drive and / or manage machinery.

3. HOW TO TAKE FLUGO

FLUGO film-coated tablets are taken orally.

Adults and children over 12 years old: 1 tablet every 6 hours. Do not take more than 4 tablets in 24 hours.

FLUGO is not used for children under 12 years old.

Patients with impaired renal function are advised to extend the interval between two doses to 8 - 12 hours.

If you take more FLUGO than you should

If you have used more FLUGO than the prescribed amount, or if the children take it accidentally contact your doctor or pharmacist immediately!

In case of overdose please contact your doctor or seek urgent medical help even if you are feeling well and do not have any clear symptoms of overdose because there is a risk of severe subsequent liver damage.

Symptoms of the overdose are: restlessness, confusion, anxiety, nausea, vomiting, stomach pain, drowsiness, hallucinations, enlargement of the pupil, high blood pressure, rapid heartbeat, increased body temperature, dry mouth and redness of the face.

If you forget to take FLUGO

If you forget a dose, take the next dose when it is the usual time to take it.

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

If you stop taking FLUGO

Use this medicine for as long as your doctor has told you.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, FLUGO can cause side effects, although not everybody gets them.

The incidence of adverse reactions is as follows:

Very common:	occur in more than 1 in 10 users.
Common:	occur in less than 1 in 10, but more than 1 in 100 users.
Uncommon:	occur in less than 1 in 100 users but more than 1 in 1.000 users.
Rare:	occur in less than 1 in 1.000, but more than 1 in 10.000 users.
Very rare:	occur in less than 1 in 10.000 users, including isolated cases.
Unknown	incidence rate of adverse reactions cannot be estimated from available data.

Stop taking FluGo immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset,
- feeling sick,
- vomiting,
- confusion,
- seizures,
- changes in vision.

Stop taking FLUGO and seek immediate medical attention:

- if you notice rashes or difficulty in breathing, swelling of the face, lips, tongue or throat (severe allergic reactions);
- if suddenly, you have high body temperature (fever), with widespread rashes and numerous small pustules (like acne), as these may be symptoms of a severe skin reaction, known as generalized acute exanthematous pustulosis - AGEP (see section 2.).

Side effects of Paracetamol

Common

Skin and subcutaneous tissue disorders: itching.

Gastrointestinal disorders: constipation, confusion, vomiting.

Nervous system disorders: headaches, insomnia, anxiety.

Respiratory disorders: lack of air in the lungs.

Rare

Disorders of the blood and lymphatic system: Thrombocytopenia (decrease in platelet count), leukopenia and neutropenia (decrease in white blood cell count).

Immune system disorders: anaphylaxis.

Very rare cases of severe skin reactions have been reported (generalized acute exanthematous pustulosis – AGEP, Stevens-Johnson syndrome, toxic epidermal necrolysis).

Unknown

Liver damage (when taken in high doses).

Respiratory disorders: pneumonia.

Side effects of Pseudoephedrine hydrochloride:

Common

Cardiac and vascular disorders: high blood pressure, heart rhythm disorder.

Gastrointestinal disorders: nausea, vomiting.

Psychiatric disorders: headaches, difficulty in sleeping, worry, anxiety, nervousness.

The effects of pseudoephedrine on the central nervous system are more common in children and the elderly.

Rare

Psychiatric disorders: hallucinations.

Skin and subcutaneous disorders: redness, sweating.

Very rare

Kidney and urinary system disorders: urine retention.

Eye disorders: glaucoma.

Unknown:

Atrial fibrillation (heart rhythm disorder), myocardial infarction (heart attack), premature beating in the ventricles (chambers) of the heart.

Severe cutaneous reactions, including acute generalized exanthematous pustulosis (AGEP).

Disorders of the immune system: over-sensitivity reaction.

Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

Side effect of chlorpheniramine maleate:

Common

Nervous system disorders: tinnitus, drowsiness, headache, dizziness, impaired psychomotor activity.

Gastrointestinal disorders: constipation, diarrhea, nausea, vomiting, dry mouth.

Eye disorders: blurred vision.

Kidney and urinary system disorders: urine retention.

Rare

Cardiac and vascular disorders: low blood pressure, heart rhythm disorder.

Nervous system disorders: confusion, depression, sleep disorders, tremors, cramps, extrapyramidal effects.

Immune system disorders: hypersensitivity reactions (including bronchospasm, angioedema, anaphylaxis, rash and photosensitivity reactions).

Blood and lymphatic system disorders: blood disorders.

Liver and gallbladder disorders: liver activity disorders.

Eye disorders: glaucoma.

Frequency unknown

Skin and subcutaneous tissue disorders: Exfoliative dermatitis (rash and peeling of the skin).

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FLUGO

Keep out of the sight and reach of children.

Do not use FLUGO after the expiry date which is stated on the package.

Do not store above 25°C.

6. OTHER INFORMATION

What FLUGO film-coated tablets contain

The active substances are Paracetamol, Pseudoephedrine hydrochloride and Chlorpheniramine maleate.

One film-coated tablet contains Paracetamol 251 mg, Pseudoephedrine hydrochloride 61.2 mg, Chlorpheniramine maleate 2.54 mg.

The excipients are: Microcrystalline cellulose, colloidal silica anhydrous, sodium starch glycolate, talc, magnesium stearate, pregelatinized starch, povidone, polyvinyl alcohol, titanium dioxide, macrogol.

Content of the pack:

Carton box with 10 tablets or carton box with 20 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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