

Package leaflet: Information for the patient

Reli-Flu

Ibuprofen 200 mg and Pseudoephedrine Hydrochloride 30 mg

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine 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 Reli-Flu is and what it is used for
2. What you need to know before you take Reli-Flu
3. How to take Reli-Flu
4. Possible side effects
5. How to store Reli-Flu
6. Contents of the pack and other information

1. What Reli-Flu is and what it is used for

Reli-Flu is used for the relief of nasal/sinus congestion with headache, fever and pain associated with the common cold and flu. This medicine contains ibuprofen, a Non-Steroidal Anti-Inflammatory Drug (NSAID) which works by relieving pain and reducing high temperature and fever. The tablets also contain pseudoephedrine hydrochloride, a decongestant, which helps clear the nasal passages and ease nasal congestion. Only use this product if you have a blocked nose together with headache, pain and/or fever. Do not use it if you have only one of the symptoms.

2. What you need to know before you take Reli-Flu

Do not take Reli-Flu

- If you are allergic to or have previously experienced skin rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips or tongue on taking ibuprofen, aspirin/ acetylsalicylic acid, other NSAIDs, or any ingredients contained in this product. See section 6.
- If you suffer from, or have suffered from stomach ulcers, stomach bleeding or perforation in the past.
- If you suffer from diabetes, prostate problems, thyroid disease, glaucoma or pheochromocytoma (i.e. tumour on the adrenal gland).
- If you have severe kidney disease (kidney failure), severe liver disease, heart disease, severe heart failure, high blood pressure or circulatory problems (angina).
- If you are taking medicine for the treatment of depression called mono-amine oxidase inhibitors or tricyclic anti-depressants (or if you have taken them in the past 14 days).
- If you have any other bleeding problems.
- If you have a history of stroke.
- If you are taking other NSAIDs, pain relievers, or decongestants.
- If you are under 12 years of age.
- If you are pregnant or breast feeding.

Inform your doctor if you have or ever had any of the above mentioned conditions before treatment with Reli-Flu starts.

Warnings and precautions

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

Talk to your doctor or pharmacist before taking Reli-Flu :

- If you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- If you are suffering from bleeding disorders.
- If you are suffering from stomach ulcers or inflammatory bowel disease (e.g. ulcerative colitis or Crohn's disease).
- If you are asthmatic, suffer from allergies.
- If you have disease of the heart, kidney, liver or prostate.
- If you are elderly – elderly people are more likely to experience unwanted side effects such as stomach bleeding and perforation which may be fatal.
- If you have Systemic Lupus Erythematosus (SLE) – an illness affecting the immune system causing joint pain, skin changes and other problems.
- If you are trying to become pregnant.
- If you are dehydrated 12-17 years old as there is a risk of kidney problems. Therefore ask a doctor before use if a 12-17 year old has not been drinking fluids or has lost fluids due to continuous vomiting or diarrhoea.

If any of these apply to you, talk to your doctor.

Drinking alcohol should be avoided during treatment. Pseudoephedrine hydrochloride may cause a positive reaction in tests conducted during anti-doping checks.

If you develop a feverish generalised erythema (redness of the skin) associated with pustules, stop taking Reli-Flu and contact your doctor or seek medical attention immediately. See section 4.

During chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

Children and adolescents

Reli-Flu is for use by adults and adolescents over 12 years of age. Reli-Flu is not for use in children younger than 12 years.

Other medicines and Reli-Flu

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

Do not use this medicine if you are taking:

- Other NSAID painkillers.
- Decongestants (nasal or oral).
- Or have taken in the last two weeks drugs for depression known as Monoamine Oxidase inhibitors (MAOIs).
- Tricyclic antidepressants (used to treat depression).

Talk to your doctor or pharmacist if you are taking:

- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting (e.g. warfarin, ticlopidine or aspirin/ acetylsalicylic acid)).
- Medicines to reduce high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan) or any water tablets (diuretics).
- Cardiac glycosides such as digoxin (digitalis) or quinidine for a heart condition.
- Phenytoin (a medicine for epilepsy).
- Lithium (used to treat mood disorders).
- Methotrexate (used to treat arthritis).
- Antacids (used to treat symptoms of stomach ulcers e.g. heartburn).
- Cyclosporins (used to suppress the body's immune system e.g. following a transplant).
- Mifepristone (used in pregnancy terminations).
- Quinolone antibiotics (used to treat a wide range of infections).
- Tacrolimus (a transplant drug).
- Medicines known as sulfonylureas such as glibenclamide (used to treat diabetes).
- Corticosteroids (a type of anti-inflammatory drug e.g. hydrocortisone).
- Selective serotonin reuptake inhibitors (SSRIs e.g. fluoxetine) (used to treat depression).
- Aminoglycosides (e.g. gentamicin or amikacin) (used to treat infections).
- The antibacterial agent furazolidone (used to treat infections).
- Zidovudine (used to treat HIV).
- Guanethidine, reserpine or methyl dopa (medicines for heart and circulation problems).
- Sulfapyrazone and probenecid (used to treat gout).
- Potassium sparing diuretics (used to treat heart problems).
- Ergot derivatives (medicines to treat migraines).
- Dopamine receptor agonists (used to treat Parkinson's symptoms).
- Heparins, Ginkgo biloba (treatment of blood clots).

If you are having an anaesthetic, stop treatment beforehand and inform the anaesthetist.

Some other medicines may also affect or be affected by the treatment of Reli-Flu. You should therefore always seek the advice of your doctor or pharmacist before you use Reli-Flu with other medicines.

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding

This product should not be taken if you are pregnant or breastfeeding.

If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Fertility

Ibuprofen belongs to a group of medicines, NSAIDs, which may impair fertility in women. This effect is reversible upon stopping the medicine. It is unlikely that ibuprofen, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

There are no known effects on driving or on use of machines. This medicine may cause side effects such as dizziness, hallucinations, unusual headaches and visual or hearing disturbances in some people. If you are affected by any of these side effects it is best not to drive or use machinery.

3. How to take Reli-Flu

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

The recommended dose is: 1 or 2 tablets every 4 to 6 hours as required. The tablets should be taken with water. Take only as much as you need and leave at least 4 to 6 hours between each dose. Do not take more than 6 tablets in any 24 hour period. If symptoms persist for more than 3 days, contact your doctor.

Do not exceed the stated dose.

Method of administration

For oral administration and short term use only.

Use in children and adolescents

Do not give to children under 12 years of age.

Adults, elderly and children over 12 years of age: The minimum effective dose should be used for the shortest time necessary to relieve symptoms.

If you take more Reli-Flu than you should

If you have taken more of this medicine than you should or if a child has accidentally taken Reli-Flu, contact your doctor or pharmacist immediately.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

Discontinue use in the case of accidental overdose.

If you forget to take Reli-Flu

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

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.

You can reduce the chances of experiencing side effects by using the minimum dose required.

If you experience any of the following side effects then STOP taking this medicine immediately and contact your doctor or pharmacist:

Common: bleeding of the stomach or bowel (vomiting blood or blood in faeces, black discoloration of faeces).

Uncommon: severe headaches or headaches that are worse than usual.

Very Rare: heart attack; fast heartbeat or palpitations; allergic reaction to Ibuprofen/Pseudoephedrine hydrochloride tablets, signs include skin rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips or tongue; blistering lesions on the skin or mucous membranes such as the inside of your mouth, signs include burning feeling, with redness, blisters and ulcers.

Not Known: stroke; behavioural problems such as feeling excited, agitated, anxious, restless or nervous; sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis -AGEP) may occur within the first 2 days of treatment with Ibuprofen/Pseudoephedrine hydrochloride tablets (See section 2). Stop using Reli-Flu if you develop these symptoms and contact your doctor or seek medical attention immediately.

In addition to the above, the following side effects may occur during treatment:

Common: indigestion, stomach ache, feeling sick (nausea), vomiting, diarrhea, constipation, wind.

Uncommon: stomach ulcer; not being able to sleep; feeling drowsy or tired; feeling dizzy or irritable; problems with your sight; headaches that do not go away; breakouts on the skin (rash, itching); inflamed stomach or bowel; worsening of existing inflammatory bowel disease; hypersensitivity such as wheezing and difficulty breathing in patients who have ever had bronchial asthma or allergic disease.

Rare: kidney problems; hearing disturbances (tinnitus).

Very Rare: depression; heart failure; kidney failure; high blood pressure; sore or inflamed mouth; inflamed pancreas (pancreatitis); narrowing of the gut (intestinal stricture); aseptic meningitis, worsening of infectious inflammations; problems with your blood cells – you may be more likely to bruise or get infections; liver problems including abnormal liver function, hepatitis or jaundice (yellowing of the skin or eyes).

Not Known: chest pain; dry mouth, feeling thirsty; abnormal spasm, seizures; spinning sensation (vertigo); Haematocrit decreased and haemoglobin decreased; seeing or hearing things that are not there (hallucinations); skin rash, red or purple skin discoloration, fluid retention (oedema); passing urine less often, blood or protein in your urine (shown in tests); a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

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 Reli-Flu

- 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 blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from light and humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Reli-Flu contains

The active substances are ibuprofen 200mg, pseudoephedrine hydrochloride 30mg.

The other ingredients are:

Core: pregelatinized starch, colloidal silica anhydrous, croscarmellose sodium, magnesium stearate, microcrystalline cellulose.

Tablet Coating: hypromellose, polyethylene glycol, titanium dioxide (E171), red iron oxide (E172).

What Reli-Flu looks like and contents of the pack

Reli-Flu tablets are pink oblong film-coated tablets.

Reli-Flu tablets are supplied in blister packaging of 20 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon

P.O. Box 90201 Jdeidet-El-Metn, Lebanon

Contact us: pharmaline@maliatrup.com

Reli-Flu Reg. N° in Lebanon: 187818/ 1

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers

Union of Arab Pharmacists

This leaflet was last revised in February 2019.

DESTINATION LOCAL

DIMENSIONS 165 x 690 mm

COLOR BLACK