

Package leaflet: information for the user

LEVIOFLU

500 mg/60 mg effervescent tablets

paracetamol/pseudoephedrine hydrochloride

Equivalent Medicine

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 or pharmacist has 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, even not listed in this leaflet, talk to your doctor or pharmacist.

What is in this leaflet:

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

1. What LEVIOFLU is and what it is used for

LEVIOFLU contains paracetamol, an analgesic that acts relieving pain and lowering fever, and pseudoephedrine, a decongestant, acting on the nasal mucosa releasing stuffy nose.

LEVIOFLU is a painkiller, antipyretic and nasal decongestant, and is used in the treatment of cold and flu symptoms.

2. What you need to know before you use LEVIOFLU

Do not use LEVIOFLU:

- if you are allergic to paracetamol, pseudoephedrine hydrochloride or any of the components of the product (listed in section 6)
- during pregnancy and lactation
- in case of children below 12 years of age
- if you have a deficiency of the enzyme glucose-6-phosphate dehydrogenase (which can lead to the destruction of red blood cells in the blood)
- if you suffer from a severe form of the following diseases:
 - coronary heart disease (angina, previous heart attack);
 - hypertension (high blood pressure);
 - arrhythmias (heart rhythm disorder or heart rate);
 - hepatic insufficiency (impairment of liver function);
 - kidney failure (renal impairment);
 - hyperthyroidism (overactive thyroid);
 - Asthma;
 - diabetes;
 - urination disorders caused by prostatic hypertrophy or other diseases;
 - glaucoma (increased pressure within the eye);
 - hemolytic anemia (destruction of red blood cells in the blood).
- if you are treated with dihydroergotamine or monoamine oxidase inhibitors (medicines used to treat depression) or have discontinued this treatment for less than two weeks because of the risk of hypertensive crisis (see section "Other medicines and LEVIOFLU").

Warnings and precautions

Ask your doctor or pharmacist before taking LEVIOFLU.

During treatment with LEVIOFLU, before taking any other medicine, control that it does not contain paracetamol because if this active substance is taken in high doses may cause serious side effects.

It may experience hepatotoxicity (capacity that have some substances to procure a damage to the liver) with paracetamol even at therapeutic doses, after a short-term treatment and in patients without pre-existing liver dysfunctions.

Caution is also recommended in patients with a history of sensitivity to aspirin and/or nonsteroidal anti-inflammatory drugs (NSAIDs).

Its use requires a careful examination in the elderly and in people who have or develop one of the following conditions:

- coronary heart disease (angina, previous heart attack);
- hypertension (high blood pressure);
- arrhythmias (heart rhythm disorder or heart rate);
- hepatic insufficiency (impairment of liver function);
- kidney failure (renal impairment);
- hyperthyroidism (overactive thyroid);
- Asthma;
- diabetes;
- urination disorders caused by prostatic hypertrophy or other diseases;
- glaucoma (increased pressure within the eye);
- hemolytic anemia (destruction of red blood cells in the blood);
- deficiency of the enzyme glucose-6-phosphate dehydrogenase (which can lead to the destruction of red blood cells in the blood).

Children and adolescents

LEVIOFLU is contraindicated in children below 12 years of age.

Other medicines and LEVIOFLU

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

In particular, tell your doctor or pharmacist if you are taking:

- any other medicine containing paracetamol, because if this active substance is taken in high doses may cause serious adverse reactions;
- analgesics, antipyretics, since concomitant use may result in the risk of serious side effects;
- oral anticoagulants, in this case it is advisable to reduce the doses;
- rifampicin, an antibiotic used to treat infections;
- cimetidine, a medicine used for the treatment of gastrointestinal diseases (esophagus, stomach and duodenum);
- anti-epileptic drugs such glutethimide, phenobarbital, carbamazepine;
- flucloxacillin, an antibiotic used to treat infections;
- cytotoxic drugs, which inhibit the growth of tumors and fight;
- domperidone and metoclopramide, indicated especially in the treatment of vomiting;
- lipid-lowering drugs, for the treatment of high cholesterol;
- monoamine oxidase inhibitors (MAOIs), medicines used to treat depression, as you may experience severe hypertensive reaction. It is contraindicated concurrent use if you stop treatment with MAOIs within the last two weeks;
- dihydroergotamine, since the combination can cause a dangerous increase in blood pressure;
- linezolid, an antibiotic used to treat infections, since the combination can cause a rise in blood pressure;
- methyldopa, a medication used to treat high blood pressure, as you may experience a reduction in the antihypertensive effect of methyldopa;
- midodrine, a medication used to treat low blood pressure, as you may experience an increase in hypertensive effect of midodrine;

- sympathomimetic drugs, mainly used for treating asthma and asthmatic bronchitis, since they may experience hypertensive episodes;
- guanethidine, a medication used to treat high blood pressure, since the antihypertensive effect may occur cancellation.

LEVIOFLU with food, drink and alcohol

Patients taking paracetamol should avoid use of alcoholic beverages because alcohol increases the risk of liver injury.

When using LEVIOFLU it is not recommended to drink bitter orange soda, because it can trigger a severe crisis hypertensive (high blood pressure).

Pregnancy and lactation

LEVIOFLU is contraindicated in pregnancy, known or suspected, and while breastfeeding.

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.

Driving and using machines

LEVIOFLU does not affect ability to drive or use machines.

LEVIOFLU contains sodium, sorbitol and aspartame.

This medicine contains about 14 mmol (324 mg) of sodium for each effervescent tablet. To be considered in patients with reduced kidney function or patients on a controlled sodium diet.

This medicine contains sorbitol. If your doctor has an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains aspartame which is a source of phenylalanine. It may be harmful for people with phenylketonuria, a genetic disease where a substance lacks (phenylalanine hydroxylase), which converts phenylalanine into another substance (tyrosine). In these patients there is an accumulation of phenylalanine in the organs, especially the brain, resulting in mental retardation.

For those sportsmen: the use of the drug without therapeutic necessity constitutes doping and may result still positive doping tests.

3. How to take LEVIOFLU

Always take this medicine exactly as reported in this leaflet or according to the instructions of your doctor or pharmacist. You should check with your doctor or pharmacist.

The recommended dose for adults and children over 12 years of age is one tablet up to three times a day.

The product should be taken with food, after meals.

Dissolve the effervescent tablet in a glass of water and drink immediately the solution thus obtained.

Do not exceed the prescribed dose unless recommended by your physician.

Caution:

Use the medicine for 5 days of therapy at the maximum, if you are an adult;

Use the medicine for 3 days of therapy at the maximum, if you administer it to an adolescent (12-18 aged).

Use in children and adolescents

LEVIOFLU is contraindicated in children below 12 years age.

If you take more LEVIOFLU than you should

If you accidentally take a higher dose than the recommended one, immediately notify your doctor or go to a hospital as a paracetamol overdose can cause irreversible damage to liver function and, less frequently, renal function damage.

In case of overdose, the following symptoms are observed: high blood pressure, extrasystoles (accelerated heart rate), tachycardia (increased frequency of heart beats), nausea and vomiting, signs of acute hepatotoxicity, mydriasis (dilated pupils), hypertension, agitation/anxiety, sinus arrhythmia (irregular heartbeats), hallucinations, tremors/hyperreflexia (increased nerve reflexes); less frequently hyperglycemia (increased blood sugar), rhabdomyolysis (breakdown of muscle cells), acute renal failure.

As an emergency treatment it is recommended: rapid gastric emptying; administration of activated charcoal. It is recommended early administration of paracetamol antidote (N-acetylcysteine).

If you have any doubt about use of LEVIOFLU, ask your doctor or pharmacist.

If you forget to take LEVIOFLU

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.

Side effects due to paracetamol:

- skin reactions of various types and severity including cases of multiform erythema, Stevens Johnson syndrome, toxic epidermal necrolysis, acute generalized pustular rash;
- hypersensitivity reactions (allergy) such as angioedema (sudden swelling of the skin and mucous membranes), laryngeal edema (swelling of the vocal cords, which does not allow the entry of air into the lungs), anaphylactic shock (severe and sudden drop of pressure);
- thrombocytopenia (low blood platelet counts), leucopenia (low white blood cells), anemia (low red blood cell count), agranulocytosis (severe reduction of a group of white blood cells, called granulocytes);
- changes in liver function and hepatitis;
- alterations in the kidney (acute renal failure, interstitial nephritis (kidney inflammation), haematuria (blood in urine), anuria (absence or extreme reduction in the amount of urine produced over 24 hours, about 100 cc));
- alterations of cardiac function;
- respiratory disorders;
- gastrointestinal reactions;
- dizziness.

Side effects due to pseudoephedrine:

- dizziness;
- headache;
- nausea;
- vomiting;
- sweating;
- thirst;
- tachycardia (increased heart rate);
- changes in blood pressure;
- precordial pain (ie in the chest over the heart);
- palpitations;
- difficulty urinating;
- muscle weakness;

- tremors;
- anxiety, agitation, nervousness, irritability, confusion, hallucinations;
- insomnia;
- high blood pressure;
- dry mouth;
- mydriasis (dilated pupils);
- gastric problems;
- ventricular arrhythmias;
- difficulty urinating in patients with prostatic hypertrophy.

Compliance with the instructions contained in the explanatory leaflet reduces the risk of side effects. These side effects are usually transient.

When they occur, it is advisable for you to consult your doctor or pharmacist.

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 at the website; <http://www.agenziafarmaco.gov.it/it/responsabili>.

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

5. How to store LEVIOFLU

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 label after EXP.

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

The expiry date refers to the sealed container when properly stored.

Do not store above 25 ° C.

After first opening of the container, the product should be used within 50 days; after this period, the remaining product should be discarded.

Keep the tube tightly closed. Store in the original package to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

It is important to always have the product information, thus keep both the box and the package leaflet.

6. Contents of the pack and other information

What LEVIOFLU contains

- The active substances are: paracetamol and pseudoephedrine hydrochloride.
- The other components are: anhydrous citric acid, **sodium** bicarbonate, **sodium** carbonate anhydrous, **sorbitol**, lemon flavor, **aspartame**, saccharin **sodium**, simethicone, leucine, docusate **sodium**.

What LEVIOFLU looks like and contents of the pack

LEVIOFLU is in form of effervescent tablets.

Package of 1 tube containing 8 tablets.

Marketing Authorization Holder

Aesculapius Farmaceutici S.r.l. – Via Cefalonia, 70 – 25124 Brescia

Manufacturer

E-Pharma Trento S.p.A. – Frazione Ravina, Via Provina 2 – 38123 Trento

This leaflet was last revised on March 2017