

PACKAGE LEAFLET: INFORMATION FOR THE USER

pharmagrip capsules

Paracetamol/Phenylephrine hydrochlorure/Chlorphenamine maleate

What is in this leaflet:

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

1. What pharmagrip capsules is and what it is used for

Pharmagrip capsules is a combination of paracetamol (an analgesic that reduces pain and fever), chlorphenamine (an antihistamine that relieves nasal secretion) and phenylephrine (that acts reducing nasal congestion).

This medicine is indicated for relief of the symptoms of cold or flu conditions associated with mild or moderate pain, fever and nasal congestion and secretion in adults and children aged 12 years and over.

You must talk to a doctor if you do not feel better or if you feel worse or if fever persists after three days or pain after five days.

2. What you need to know before you take pharmagrip capsules

Do not take pharmagrip capsules:

- If you are allergic to paracetamol, phenylephrine hydrochloride, chlorphenamine maleate or any of the other ingredients of this medicine (listed in section 6).
- If you have high blood pressure (arterial hypertension).
- If you have any thyroid disease (hyperthyroidism).
- If you suffer any liver disease or severe kidney disease.
- If you suffer any serious heart or artery disease (such as serious coronary disease or angina pectoris).
- If you suffer from diabetes mellitus.
- If you suffer tachycardia (fast heartbeats).
- If you are taking any medicine that inhibits monoamine oxidase (MAOI) (for example some medicines for depression or Parkinson's disease).
- If you are taking sympathomimetics (medicines used in asthma treatment, or medicines used to increase heartbeats rate).
- If you are taking beta-blockers (heart medicines or medicines to treat arteries diseases (See: Other medicines and **Pharmagrip capsules**))
- If you suffer glaucoma (increased ocular pressure).
- Do not use in children under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking **Pharmagrip capsules**.

Do not exceed the dose recommended in section (3. *How to take pharmagrip capsules*).

In chronic alcoholics, care should be taken not to take more than 2 g of paracetamol a day (4 capsules of **pharmagrip capsules**).

It should be avoided the simultaneous use of this medicine with other medicines containing paracetamol as high doses of paracetamol can lead to liver damage. Do not take more than one medicine that contains paracetamol without asking your doctor.

Ask your doctor before taking this medicinal product:

- In patients with kidney, liver, heart or lung diseases and in patients with anaemia.
- Asthmatic patients who are sensitive to acetylsalicylic acid.
- Patients sensitive (allergic) to an antihistamine, because they may be sensitive to others antihistamine (such as chlorphenamine).
- The patients who are being treated with medicines for: prostate hypertrophy, bronchial asthma, very slow heartbeats, hypotension, brain atherosclerosis, inflammation of the pancreas (pancreatitis), digestive ulcer (stenosing peptic ulcer), pyloroduodenal obstruction (between stomach and bowel), thyroid diseases, patients sensitive to sedative effects of certain medicines.
- If you are treated with tricyclic antidepressants or medicines with similar action and gastrointestinal problems occurs, stop taking this medicine and talk to a doctor immediately, paralytic ileus might occur (stop of normal movements of a part of the bowel).

Children and adolescents

Children under 12 years of age cannot take this medicine.

Interaction with laboratory tests:

If you are to undergo any diagnostic tests (including blood, urine tests, etc) tell your doctor that you are taking this medicine, because it may alter the results of such tests.

Other medicines and pharmagrip capsules

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

In particular, if you are using any of the following medicines it may be necessary to modify the dose of some of them or space administration at least 15 days apart or discontinue treatment:

- Medicine for epilepsy: Anti-epileptic agents (lamotrigine, phenytoin or other hydantoin, phenobarbital, methylphenobarbital, primidone, carbamazepine).
- Antituberculosis medicines (isoniazid, rifampicin).
- Medicines for seizures and depression (barbiturates), used as hypnotics, sedatives and anticonvulsants.
- Medicine used to avoid blood clots: Oral anticoagulants (acenocoumarol, warfarin).
- Some medicines used to increase urine output (loop diuretics such as furosemide or other diuretics) and other diuretics that cause potassium depletion (such as diuretics used to treat hypertension, or others).
- Medicines used to prevent nausea and vomiting (metoclopramide and domperidone).
- Medicines used to treat gout (probenecid and sulphapyrazone).
- Medicines used to treat high blood pressure (hypertension) and disorders in heart rhythm (arrhythmias) (propranolol).
- Medicines used to lower blood cholesterol (cholestyramine).
- Medicines used to treat depression, Parkinson's disease or other illnesses (Monoamine oxidase inhibitors (MAOIs). The administration of **pharmagrip capsules** must be postponed for at least 15 days after ending treatment with such medicine.
- Medicines for migraine, or others for labour, blood pressure or other conditions (alpha-adrenergic blockers).
- Alpha- and beta-adrenergic receptor blockers, such as labetalol and carvedilol (used for heart conditions or arterial diseases).

- Medicines used to treat depression (tricyclic antidepressants and tetracyclic antidepressants).
- General anaesthetics.
- Antihypertensive drugs (blood pressure-lowering agents).
- Medicines used for the heart, such as cardiac glycosides and antiarrhythmics.
- Medicines containing thyroid hormones (used for thyroid diseases).
- Medicines used to treat heart conditions or digestive disorders (atropine sulphate).
- Medicines that cause central nervous system depression (such as those used for insomnia, anxiety or other antidepressants).
- Ototoxic medicines (they have as adverse effect that they damage the ear).
- Photosensitising medicines (their adverse effect is that they cause allergy to light).

Pharmagrip capsules with food, drink and alcohol

Do not drink alcohol while taking this treatment, it can improve the side effects occurrence.

The use of paracetamol by patients who regularly consume alcohol (three or more alcoholic beverages: beer, wine, spirits, a day) may cause liver damage.

In chronic alcoholics, care should be taken not to take more than 4 capsules of **pharmagrip capsules** per day (2 g of paracetamol) divided in various doses.

The medicine can be taken with or without food.

Pregnancy and breast-feeding

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.

This medicine cannot be taken during pregnancy unless your doctor considers that it is strictly necessary.

This medicine cannot be taken during breast-feeding period, it can cause side effects on the baby.

Driving and using machines

This medicine can cause drowsiness altering the mental and/or physical capacity. If you experience these effects do not drive or use tools.

3. How to take pharmagrip capsules

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

Posology

Adults and children over 12 years of age: the usual dose is 1 capsule every 6 or 8 hours (3 or 4 capsules a day). The maximum daily dose is 6 capsules.

Patients with liver and renal diseases: they should ask their doctor. (See section 2. What you need to know before you take **pharmagrip capsules**).

Use in children: do not administer to children under 12 years of age.

Use in the elderly:

Elderly patients should not take this medicine without talking to the doctor. They can be affected by some side effects, such as slow heartbeats occurrence (bradycardia) or a reduction in heart flow due to phenylephrine and chlorphenamine content. It is likely that they may have side effects such as sedation, confusion, hypotension or excitement and may be more sensitive to effects such as dry mouth and urinary retention.

Method of administration

This medicine is administered orally.

Take 1 capsule with half a glass of water preferably.

This medicine intake depends on symptoms occurrence. As the symptoms subside, the treatment should be discontinued.

If fever persists after 3 days of treatment or pain or other symptoms persist after 5 days, or the fever gets worse or some new symptoms appear, ask your doctor.

If you take more pharmagrip capsules than you should

Talk to your doctor or pharmacist immediately:

In the event of overdose, quickly report to a medical centre even if there are no symptoms, since these often manifest only after periods of up to three days, even in cases of severe overdose.

The symptoms of overdose may be: dizziness, vomiting, loss of appetite, yellow colouring of the skin and the eyes (jaundice), and abdominal pain. Anxiety, fear, restlessness, headache (may be a symptom of hypertension), seizures, insomnia (or extreme drowsiness), clumsiness, feeling faint, instability, confusion, irritability, tremor, anorexia, psychosis with hallucinations (more frequent in children). Dry mouth, nose or throat. Effects such as hypertension, arrhythmia (irregular or rapid heart beats), palpitations, diminished urinary output. Metabolic acidosis (decrease of the alkaline reserves in blood). Long-term use may lead to plasma volume depletion (lowered blood volume).

The period in which the management of paracetamol overdose offers maximum efficacy is within 4 hours after overdose.

Patients treated with barbiturates, or patients with chronic alcoholism, may be more susceptible to paracetamol overdose toxicity.

In case of overdose or accidental intake, go immediately to a medical centre, stating the medicine and amount taken.

4. Possible side effects

Like all medicines, **pharmagrip capsules** can cause side effects, although not everybody gets them.

During the period of use of paracetamol, phenylephrine and chlorphenamine, the following side effects whose frequency has not been established accurately, have been reported:

- **Common side effects that may occur:**

Slight drowsiness, dizziness, muscle weakness; these adverse events can disappear after 2-3 days of treatment. Difficulty in movements of the face, clumsiness, tremor, changes in sensations and tingling, dry mouth, loss of appetite, taste or odour disturbances, gastrointestinal disorders (that can decrease if the drug is administered together with food), nausea, vomiting, diarrhoea, constipation, stomach-ache, urinary retention, dry nose and throat, thickening of mucus, sweating, blurred vision or other sight disturbances.

- **Rare side effects that may occur:**

Malaise, drop in blood pressure (hypotension) and an increase in blood transaminase levels. Myocardial infarction, ventricular arrhythmias (irregular heartbeats), lung oedema (rise of the fluid in the lungs) and brain haemorrhage (at high doses, or in susceptible individuals).

Nervous excitement (generally with high doses and more common in the elderly and children) with symptoms such as restlessness, insomnia, nervousness or occasionally seizures. Other rare side effects that may occur are: chest tightening, noises in the lungs, fast or irregular heart beating (generally with overdoses), liver disorders (that can occur with stomach-ache, dark urine or other symptoms), allergic reaction, severe hypersensitivity reactions (cough, difficulty to swallow, fast beating, itching, swelling of the eyelids or around the eyes, face, tongue, breathlessness, etc.), sensitisation to sunlight, cross sensitivity (allergy) with drugs related to chlorphenamine Blood disorders (changes in the blood cells formula, such as agranulocytosis, leukopenia, aplastic anaemia, thrombocytopenia), with symptoms such as unusual bleeding, sore throat or tiredness; blood pressure lowering or rise, oedema (swelling), disorders in the ears, impotence, menstrual disorders.

- **Very rare side effects that may occur:**

Kidney disease, cloudy urine, allergic dermatitis (skin rash), jaundice (yellowing of the skin), blood disorders (neutropenia, haemolytic anaemia) and hypoglycaemia (lowered blood sugar levels).

Cases of severe skin reactions have been very rarely reported.

Paracetamol can cause liver damage when taken in high doses or in long term treatments. .

- **Side effects of which frequency is unknown are :**

Anxiety, irritability, weakness, increased blood pressure (hypertension,, generally with high doses and in susceptible patients), headache (with high doses, it may be a symptom of hypertension), very slow heart beat (severe bradycardia), reduction of blood vessel calibre (peripheral vasoconstriction), reduced heart performance affecting especially elderly people and patients with poor brain or coronary blood flow, possible induction or exacerbation of heart disease, urinary retention, paleness, hair erection, increased blood sugar levels (hyperglycemia), diminished blood potassium, metabolic acidosis (metabolism altered), cold limbs (legs or arms), flushing, feeling faint (hypotension). The following can be observed with high doses: vomiting, palpitations, psychotic states with hallucinations. Long-term use can lead to diminished blood volume.

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. By reporting undesirable effects, you can contribute to provide further information on the safety of this medicine.

5. How to store pharmagriP capsules

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use **pharmagriP capsules** after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. If in doubt, 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 pharmagriP capsules contain

- The active substances are: paracetamol, phenylephrine hydrochloride (equivalent to 8,21 mg of phenylephrine) and chlorphenamine maleate (equivalent to 2,8 mg of chlorphenamine).

- The other ingredients are: pregelatinised maize starch, talc (E-553b), magnesium stearate (E-470b), and colloidal anhydrous silica. The gelatine capsule is made up of: gelatine, titanium dioxide (E-171), Indigo carmine blue (E-132).

What pharmagriP capsules looks like and contents of the pack

Hard capsules with light blue lid and white body. It is packed in PVC-PVDC/Aluminium blisters. Each package contains 14 capsules in alveolar packing.

Marketing Authorisation Holder and Manufacturer

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