Package leaflet: Information for the user

pharmagrip capsules

Paracetamol/Phenylephrine hydrochloride/Chlorphenamine maleate

Read all of 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 have 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse or if the fever persists for more than 3 days or the pain lasts for more than 5 days (2 days in the case of sore throat).

What is in this leaflet:

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 (which 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 adolescents over 12 years of age.

You must talk to a doctor if you do not feel better or if you feel worse or if the fever persists for more than 3 days or the pain lasts for more than 5 days.

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

Do not take pharmagrip capsules

- If you are allergic (hypersensitive) to paracetamol, phenylephrine, chlorphenamine 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 have any serious liver or kidney disease.
- If you have any serious heart or artery disease (such as severe coronary artery disease or angina pectoris).
- If you have diabetes mellitus.
- If you have tachycardia (fast heartbeats).

- If you are being treated with a monoamine oxidase inhibitor (MAOI) drug (such as some antidepressants or medicines for treating Parkinson's disease).
- If you are being treated with sympathomimetic drugs (medicines used for treating asthma or medications to speed up your heart rate).
- If you are being treated with beta blockers (medicines for the heart or for treating artery disease) (see: ***Other medicines and pharmagrip capsules*****)**.
- If you have glaucoma (increased ocular pressure).
- Children under 12 years of age must not take this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking **pharmagrip capsules.**

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

Chronic alcoholics should take care not to take more than 2 g of paracetamol (4 capsules of **pharmagrip capsules**).

Concomitant use of this medication with other medicines containing paracetamol should be avoided since high doses could damage your liver. Do not take more than one medicine containing paracetamol without talking to your doctor.

The following patients must ask their doctor before taking this medicine:
- Patients with kidney, liver, heart or lung disease and patients with anaemia.
- Asthmatic patients who are sensitive to acetylsalicylic acid.
- Patients who are sensitive (allergic) to an antihistamine, because they may be sensitive to other antihistamines (such as chlorphenamine).
- Patients who are being treated with medications for: prostate hypertrophy, bronchial asthma, very slow heart rate, hypotension, cerebral arteriosclerosis, inflammation of the pancreas (pancreatitis), digestive ulcer (stenosing peptic ulcer), pyloroduodenal obstruction (between the stomach and the bowel), thyroid disease, patients sensitive to the sedative effects of some medicines.
- If you are being treated with tricyclic antidepressants or medicines with a similar effect and you experience gastrointestinal problems, you must stop taking this medicine and tell your doctor, as paralytic ileus could occur (stoppage of normal movements of a part of the bowel).

Children
Children under 12 years of age must not take this medicine.

<u>Interaction with laboratory tests:</u>
If you are having an analytical test (including blood and urine tests, etc.), tell you doctor that you are taking/using this medicine, since it can alter the test results.

Other medicines and pharmagrip capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might have to take 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 separate their administration by at least 15 days or discontinue treatment:

- Medicines to treat epilepsy: Anti-epileptic agents (lamotrigine, phenytoin or other hydantoins, phenobarbital, methylphenobarbital, primidone, carbamazepine).
- Medicines to treat tuberculosis (isoniazid, rifampicin).
- Medicines to treat convulsions and depression (barbiturates), used as hypnotics, sedatives and

anticonvulsants.
- Medicines to prevent blood clots: Oral anticoagulants (acenocoumarol, warfarin).
- Medicines used to increase urine output (loop diuretics such as those of the furosemide group 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 sulphinpyrazone).
- Medicines used to treat high blood pressure (hypertension) and heart rhythm abnormalities (arrhythmias) (propranolol).
- Medicines used to lower blood cholesterol (cholestyramine).
- Medicines used to treat depression, Parkinson's disease and other diseases (monoamine oxidase inhibitors (MAOIs)). The administration of **pharmagrip capsules** must be postponed for at least 15 days after ending treatment.
- Medications used to treat migraine; medicines taken for childbirth; medicines taken to treat blood pressure and other diseases (alpha-adrenergic blocking agents).
- Alpha- and beta-adrenergic receptor blockers, such as labetalol and carvedilol (used for heart conditions or to treat arterial diseases).
- Medicines used to treat depression (tricyclic and tetracyclic antidepressants).
- General anaesthetic drugs.
- Antihypertensive drugs (medicines to lower blood pressure).
- Medicines used for the heart, such as cardiac glycosides and antiarrhythmic drugs.
- Medicines containing thyroid hormones (used to treat thyroid disease).
- Medicines used for heart disease or digestive disorders (atropine sulphate).
- Medicines that cause central nervous system depression (such as those used for insomnia or anxiety).
- Ototoxic medicines (a side effect of which is damage to the ear).
- Photosensitising medicines (a side effect is that they cause allergy to light).

pharmagrip capsules with food, drink and alcohol
While being treated with this medicine, you should not drink alcoholic beverages, as it may increase the side effects of the medicine.

Moreover, the use of medicines containing paracetamol by patients who regularly consume alcohol (3 or more alcoholic beverages - beer, wine, spirits, etc. - a day) may cause liver damage**.**

This medicine can be taken with or without food.

Chronic alcoholics should take care not to take more than 4 capsules of **pharmagrip capsules** a day (2 g of paracetamol), distributed in several doses.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You must not take this medication during pregnancy unless your doctor considers it strictly necessary.

You must not take this medicine while breast-feeding, as it can have adverse effects on the baby.

Driving and using machines
This medicine may cause drowsiness, impairing mental and/or physical ability. If you notice these effects, avoid driving or using machines.

3. How to take pharmagrip capsules

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

Adults and adolescents 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 or kidney disease: Should consult their doctor (See section 2 What you need to know before you take pharmagrip capsules).

Use in children:
Children under 12 years of age must not take this medicine.

Use in elderly patients:
Elderly people should not take this medicine without talking to their doctor because they may be particularly affected by some side effects of the medicine such as the appearance of a slow heartbeat (bradycardia) or reduced cardiac output, as it contains phenylephrine and chlorphenamine. They are also more likely to experience side effects such as sedation, confusion, hypotension or excitement, and they may be more sensitive to effects such as dry mouth and urinary retention.

How to take pharmagrip capsules:
This medicine is taken orally.
Take 1 capsule with a little liquid, preferably half a glass of water.

This medicine should only be taken when symptoms are present. As the symptoms subside, the treatment should be discontinued.

If the fever lasts for more than 3 days of treatment, the pain or other symptoms persist for more than 5 days or they worsen or other symptoms appear, consult your doctor.

If you take more pharmagrip capsules than you should
Immediately contact your doctor or pharmacist:

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

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 intense drowsiness), clumsiness, feeling faint, instability, confusion, irritability, tremor, anorexia, psychosis with hallucinations (especially in children). Dry mouth, nose or throat. Effects such as high blood pressure, arrhythmia (irregular or rapid heartbeat), palpitations, reduced urine production. Metabolic acidosis (decreased alkaline reserves in the blood). Long-term use may lead to plasma volume depletion (lowered blood volume).

The period in which the management of overdose offers maximum efficacy is within four hours after an overdose of the medicine.

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

In case of overdose or accidental intake, report immediately to a medical centre or call the Toxicology Information Service, phone number 91 562 04 20, specifying the medicine and the amount taken.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported while taking paracetamol, phenylephrine and chlorphenamine, though their frequency has not been clearly established:

- **Common side effects:**

Slight drowsiness, dizziness, muscle weakness; these side effects can disappear after 2-3 days of treatment. Difficulty moving the face, clumsiness, tremor, changes in sensations and tingling, dry mouth, loss of appetite, taste or smell disturbances, gastrointestinal problems (which 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:**

Malaise, low blood pressure (hypotension) and increased blood transaminase levels. Myocardial infarction, ventricular arrhythmia (irregular heartbeat), pulmonary oedema (increased volume of 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), which can include symptoms such as: restlessness, insomnia, nervousness and even seizures. Other uncommon side effects include: chest tightening, noises in the lungs, fast or irregular heartbeat (generally with overdoses), liver disorders (that can occur with stomach ache, dark urine or other symptoms), allergic reaction, severe hypersensitivity reactions (cough, difficulty swallowing, fast heartbeat, itching, swelling of the eyelids or around the eyes, face, tongue, difficulty breathing, etc.), photosensitivity (sensitisation to sunlight), cross sensitivity (allergy) with chlorphenamine-related drugs. Blood disorders (changes in the composition of the blood cells such as agranulocytosis, leukopenia, aplastic anaemia, thrombocytopenia) with symptoms such as unusual bleeding, sore throat or tiredness; decrease or increase in blood pressure, oedema (swelling), hearing disorders, impotence, menstrual disorders.

- **Very rare side effects:**

Kidney disease, cloudy urine, allergic dermatitis (skin rash), jaundice (yellow skin colour), blood abnormalities (neutropenia, haemolytic anaemia) and hypoglycaemia (low blood sugar).

Paracetamol may damage the liver when taken at high doses or during prolonged treatments. Very rarely cases of severe skin reactions have been reported.

- **Side effects of unknown frequency:**

Anxiety, irritability, weakness, increased blood pressure (hypertension, generally with high doses and in susceptible patients), headache (with high doses and it may be a symptom of hypertension), very slow heart beat (severe bradycardia), reduced blood vessel diameter (peripheral vasoconstriction), reduced cardiac output especially affecting 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 (hyperglycaemia), decreased blood potassium, metabolic acidosis (change in metabolism), 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 25ºC.

Do not use this medicine 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. Place the containers and medicines you no longer use in the SIGRE point of the pharmacy. 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 contains

- The active substances are paracetamol 500 mg, phenylephrine hydrochloride 10 mg. (equivalent to 8.21 mg of phenylephrine) and chlorphenamine maleate 4 mg (equivalent to 2.8 mg of chlorphenamine).
- The other ingredients are: pregelatinised maize starch without gluten, 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 powder for oral suspension looks like and contents of the pack

pharmagrip is supplied in capsule form in packs containing 14 capsules.

Marketing authorisation holder and manufacturer
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This leaflet was last revised in February 2017.

Detailed and updated information on this medicine can be found on the Spanish Medicines Agency (AEMPS) website *http://www.aemps.gob.es*