

PACKAGE LEAFLET: INFORMATION FOR THE USER
CAFFETIN® SC 250 mg/ 210 mg/ 50 mg tablets
paracetamol/ propyphenazone/ caffeine

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

This medicine is available without prescription. However, you still need to take Caffetin sc carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 5 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Caffetin sc is and what it is used for
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1. WHAT CAFFETIN SC IS AND WHAT IT IS USED FOR

Caffetin sc is a combined analgesic drug. The analgesic effect has been proven for paracetamole and propyphenazone, while caffeine may be considered as an adjuvant, which ameliorates the effect of the analgesics.

Caffetin sc is indicated for pains such as headache, toothache, migraine, postoperative and posttraumatic pain or menstrual pain.

2. BEFORE YOU TAKE CAFFETIN SC

Do not take Caffetin sc

- if you have had an allergic reaction to the drug or any of its components;
- if you have severe kidney or liver disease or virus hepatitis;
- if you are alcohol abuser;
- if you have porphyria or lack of enzyme glucoso-6-phosphate dehydrogenase, which are rare, hereditary metabolic disorders;
- if you are pregnant or breastfeeding.

Caffetin sc should not be used in children under 12 years old.

Take special care with Caffetin sc

- if you have renal, liver or chronic respiratory diseases, including asthma;
- if you have bone marrow suppression;
- if you have a blood disorder;
- if you have a peptic ulcer or gastrointestinal bleeding;
- if you are hypersensitive to other analgesics (because of the danger of provoking asthma attacks);

Caution should be exercised when the drug is used by children (aged over 12 years).

In patients with bone marrow suppression, close surveillance for haematological parameters is recommended. If such reaction occurs following Caffetin sc use (increased temperature, sore throat, ulceration and abscesses in the mouth, periannal abscesses, as well as reduction of blood granulocytes), the use of the drug should be discontinued immediately. If palpitations or tachycardia occur, the treatment should be discontinued.

Analgesics should not be taken in case of severe abdominal pain before a doctor has been consulted, as they may mask important symptoms, thus rendering a diagnosis more difficult. If analgesics have been taken, the doctor has to be informed.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

There is no evidence about specific interactions of Caffetin sc with other drugs having significant clinical implications.

Simultaneous administration is not recommended with CNS-stimulant drugs, MAO-inhibitors and drugs or beverages containing caffeine.

Alcohol, phenobarbital, phenytoin, carbamazepine, isoniazide and rifampicin enhance the hepatotoxicity of paracetamol. If paracetamol preparations are used concomitantly with Caffetin sc, the risk of paracetamol overdosing is possible.

Concomitant use with oral anticoagulants (blood thinners) or NSAIDs may lead to undesirable gastrointestinal adverse reactions.

Taking Caffetin sc with food and drink

Caffetin sc tablets could be taken with or without food. During Caffetin sc use, beverages containing alcohol should not be used.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Caffetin sc tablets should not be used during pregnancy and lactation.

Driving and using machines

Caffetin sc administered in therapeutic doses does not affect the driving ability or operating machinery.

3. HOW TO TAKE CAFFETIN SC

Always take Caffetin sc exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Caffetin sc as a combined analgesic should be used as needed, and it is not intended for long-term therapy.

Adults and children over 16 years old: the single dose is 1-2 tablets, according pain intensity. The dose should be repeated 3 times daily. The maximal daily dose is 6 tablets.

Children 12-16 years old: ½-1 tablet, with a possibility to repeat the dose 3 times daily.

If the pain persists or if the use of Caffetin sc fails to produce the expected result consult a doctor as soon as possible. The treatment with Caffetin sc should not be longer than 5-7 days without a medical advice.

If you take more Caffetin sc than you should

If you have taken more than you should, contact your doctor or pharmacist immediately.

Since the drug contains paracetamole, in case of overdosage severe liver or renal damage may occur. Larger overdoses of propyphenazone or caffeine may cause a state of daze or unconsciousness, visual disturbances, cramps, over excitation and disturbances of the heart rhythm. A prompt treatment into the hospital is essential.

If you forget to take Caffetin sc

Caffetin sc should be administered only when needed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Caffetin sc can have undesirable effects, although not everybody gets them.

The therapeutic doses of Caffetin sc are well tolerated. Possible adverse effects may occur very rarely or during therapy with higher doses:

- nausea, vomiting and other gastrointestinal disturbances;
- liver and kidney disturbances;
- allergic reactions (itching, rash, urticaria, even an anaphylactic shock);
- decreased blood count or complete lack of granulocytes;
- insomnia, nervousness, tachycardia.

At the first sign of adverse-effects, the physician has to be consulted before continuing taking Caffetin sc.

If an allergic reaction (skin rash, urticaria, swelling or difficult breathing) as well as fever concomitantly with sore throat, ulceration and abscesses in the mouth and perianal area stop taking the drug and seek medical assistance immediately. These symptoms may be a manifestation of a serious side effect that occurs very rarely.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CAFFETIN SC

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Caffetin sc after the expiry date which is stated on the carton (abbreviation used for expiry date). The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Caffetin sc contains

- *The active substances are:* paracetamol, propyphenazone and caffeine.

Each tablet contains: 250 mg paracetamol, 210 mg propyphenazone and 50 mg caffeine.

- *The other ingredients are:* magnesium stearate; sodium laurilsulfate; sodium starch glycolate (type A); silica, colloidal anhydrous; povidone; calcium hydrogen phosphate dihydrate; cellulose, microcrystalline; croscarmellose sodium; glycerol dibehenate.

What Caffetin sc looks like and contents of the pack

Caffetin sc tablets are white, round, flat tablets with facet, with bisection line on one side, and trademark of the manufacturer Alkaloid (Ⓢ) impressed on the other side of the tablet.

Caffetin sc tablets are immediate packed in strip (Al/PE printed foil), each strip containing 6 or 10 tablets. The cardboard box contains 1 or 2 strips and a leaflet with information for the user.

Manufacturer

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