

PACKAGE LEAFLET: INFORMATION FOR THE USER
CAFFETIN COLD[®] film-coated tablets

Read all of this leaflet carefully as it contains important information for you.

This medicine is available without doctor's prescription. However, to get the best results from the treatment, you should follow the instructions for the use of the medicinal product carefully.

- Keep this leaflet. You may need to read it again.
- If you need further information or advice, ask your pharmacist.
- 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 effect not listed in this leaflet, please inform your doctor or pharmacist.

In this leaflet:

1. What Caffetin Cold is and what it is used for
2. Before you take Caffetin Cold
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1. WHAT CAFFETIN COLD IS AND WHAT IT IS USED FOR

Caffetin Cold is a combination preparation containing several active ingredients.

Paracetamol is an analgesic and antipyretic agent.

Pseudoephedrine reduces swelling of nasal mucosa and thus makes the nose and airways passable.

Dextromethorphan suppresses cough by reducing irritation in the throat and bronchi.

Vitamin C enhances the immune system.

Caffetin Cold relieves the symptoms of common cold and flu (headache, muscle pains, sore throat, stuffy nose, fever and cough).

2. BEFORE YOU TAKE CAFFETIN COLD

Do not take Caffetin Cold

- If you are allergic to Caffetin Cold or any of the other ingredients of Caffetin Cold;
- If you have severe hypertension, coronary artery disease, severe liver or kidney problems;
- if you are currently taking or if you have taken in preceding two weeks medicinal products from the group of MAO-inhibitors.

Take special care with Caffetin Cold

- if you have mild to moderate hypertension, heart disease, diabetes, liver or kidney disease, overactive thyroid gland (hyperthyroidism), increased intraocular pressure or enlarged prostate.

Ask your pharmacist or doctor if you can take Caffetin Cold:

- If you are over 60 years or your body is exhausted, it is more likely some of the side effects of the drug to occur.
- Do not take this medicine without talking to your doctor or pharmacist if you are taking more than three alcoholic beverages per day or if you have liver damage due to alcohol use.

Taking other medicines

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

Do not take Caffetin Cold concomitantly with other products containing paracetamol. Caffetin Cold coadministered with drugs for depression treatment can increase blood pressure and heart rate. Taken with haloperidol it can cause anxiety, irritability and sleep disturbances. The effect of Caffetin Cold may be reduced by some medications used to treat epilepsy. Caffetin Cold may potentiate the effect of oral anticoagulants (warfarin) and chloramphenicol (antibiotic).

Caffetin Cold can reduce the effect of certain medications for treatment of high blood pressure.

Taking Caffetin Cold with food and drinks

Caffetin Cold tablets can be taken without regard to food.

Avoid the use of alcohol. Taken with alcohol this medicine can cause liver damage.

Avoid co-administration with food containing caffeine because it can cause irritability and palpitation.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Your pharmacist or doctor will explain the potential benefit and risk with Caffetin Cold intake during pregnancy or lactation.

Driving and using machines

Be careful if you drive or operate machinery until you know what the effect of the medicine on you is. Caffetin Cold can cause dizziness in some people.

3. HOW TO TAKE CAFFETIN COLD

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

The usual dose of Caffetin Cold for adults and children over 12 years is one tablet four times a day. Two tablets may be taken at once. The interval between doses should not be shorter than four hours.

The maximum single dose is two tablets and the maximum daily dose is two tablets four times daily (8 tablets in 24 hours).

Do not take Caffetin Cold for more than 5 consecutive days. If your symptoms do not subside or worsen, consult your doctor.

Caffetin Cold is not recommended for use in children under 12 years.

If you take more than the necessary dose Caffetin Cold:

If you take more than recommended, you should contact your doctor or pharmacist immediately even if you feel well because of the risk of delayed serious liver damage.

If you forget to take Caffetin Cold

Taking Caffetin Cold may continue depending on the relief of symptoms. Do not take a double dose, exceeding the maximum single dose to make up for a missed dose.

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 Cold can cause side effects, although not everybody gets them.

Rarely the following side effects can occur: nausea, vomiting, diarrhea, drowsiness, anxiety, irritability, dizziness, sleep disturbances, increased blood pressure and heart rate, dry mouth, headache; extremely rare: increases in liver enzymes, pancreatitis, changes in blood count.

All medicines can cause allergic reaction. Serious allergic reactions are very rare and very rarely life-threatening. Any sudden wheezing, difficulty in breathing, swelling of eyelids, face or lips rash or itching (especially affecting the whole body) should make you consult a doctor immediately.

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 COLD

Keep out of the reach of children.

Do not use Caffetin Cold after the expiry date stated on the carton and on the blister after "EXP". The expiry date refers to the last day of the specified month.

Do not remove tablets from the blister in advance.

To be stored below 25°C.

Medicines should not be disposed of via wastewater or waste of home. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protection of the environment.

6. FURTHER INFORMATION

What Caffetin Cold contains

Every film-coated tablet contains active substances: 500 mg paracetamol, 30 mg pseudoephedrine hydrochloride, 15 mg dextromethorphan hydrobromide and 60 mg ascorbic acid.

- The other ingredients are:

Tablet core: Starch, pregelatinised; cellulose, microcrystalline; povidone; croscarmellose sodium; silicon dioxide, colloidal anhydrous; talc; magnesium stearate.

Tablet coating: Opadry white: polyvinyl alcohol–partially hydrolyzed; macrogol 3350; titanium dioxide (E171); talc.

Opadry blue: polyvinyl alcohol–partially hydrolyzed; macrogol 3350; titanium dioxide (E171); talc; FD&C blue/Indigo carmine aluminium (E132).

What Caffetin Cold looks like and what the pack contents

Caffetin Cold are blue, oblong, biconvex film-coated tablets with dividing line on one side.

Caffetin Cold tablets are packed in blisters (aluminium folio/PVC/TE/PVdC folio), containing 10 tablets.

The carton contains 10 tablets (1 blister) and a Package Leaflet.

Marketing Authorisation Holder and Manufacturer

Marketing authorization holder

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This leaflet was last approved on