

Package leaflet: Information for the user

Care Cold & Flu Relief 200mg/5mg Film Coated Tablets

Ibuprofen/Phenylephrine hydrochloride

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 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, 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.

What is in this leaflet

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1. What Care Cold & Flu Relief 200mg/5mg Film Coated Tablets is and what it is used for

Care Cold & Flu Relief 200mg/5mg Film Coated Tablets contains ibuprofen and phenylephrine hydrochloride, which are effective in relieving the symptoms associated with colds and flu, including relief of aches and pains, sore throats, headache, nasal congestion (blocked nose) and lowering of temperature.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) and is effective against aches and pains (including headache), swelling and can also reduce a fever. Phenylephrine hydrochloride (nasal decongestant) reduces swelling in the passages of the nose, relieving nasal congestion and reducing the pressure which may cause a headache.

2. What you need to know before you take Care Cold & Flu Relief 200mg/5mg Film Coated Tablets

DO NOT take this medicine if you:

- are allergic to ibuprofen, phenylephrine hydrochloride or any of the other ingredients of this medicine (see section 6), or to aspirin or other painkillers.
- have ever had a stomach ulcer, perforation or bleeding.
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines.
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs).
- are taking other NSAID painkillers.
- are taking more than 75mg of aspirin a day. If you are on a low-dose aspirin (up to 75mg daily) talk to your doctor or pharmacist before you take Care Cold & Flu Relief 200mg/5mg Film Coated Tablets.
- have severe liver or kidney problems.
- have severe heart problems (severe heart failure), high blood pressure or blood coagulation disorder.
- have breathing difficulties.
- have prostate problems.
- have an overactive thyroid.
- are taking or have taken within the last 14 days a medicine called a monoamine oxidase inhibitor (usually used to treat depression).
- are in the last 3 months of pregnancy.
- are under 12 years old.

Warnings and precautions

Talk to your doctor or pharmacist before taking Care Cold & Flu Relief 200mg/5mg Film Coated Tablets if you:

- have or have had asthma.
- have kidney, heart, liver or bowel problems.
- have high cholesterol or previously have had a heart attack or stroke.
- have a history of gastrointestinal disease (such as ulcerative colitis or Crohn's disease).
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes or other organ disorders).
- are a smoker.
- are in the first 6 months of pregnancy.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a **small increased risk of heart attack (myocardial infarction) or stroke**, particularly when used at high doses and/or prolonged treatment.

Do not exceed the recommended dose or duration of treatment (10 days).

Skin reactions

Serious skin reactions have been reported in association with Care Cold & Flu Relief 200mg/5mg Film Coated Tablets treatment. You should stop taking Care Cold & Flu Relief 200mg/5mg Film Coated Tablets and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

You should discuss your treatment with your doctor or pharmacist before taking Care Cold & Flu Relief 200mg/5mg Film Coated Tablets if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Other medicines and Care Cold & Flu Relief 200mg/5mg Film Coated Tablets

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

To reduce the risk of side effects, do not take this medicine with other NSAID containing products (e.g. aspirin, ibuprofen). If you are on low-dose aspirin (up to 75mg daily) talk to your doctor or pharmacist before you take this medicine.

Care Cold & Flu Relief 200mg/5mg Film Coated Tablets may affect or be affected by some other medicines. For example, avoid taking this medicine with medicines:

- used for the treatment of asthma and various inflammatory conditions (corticosteroid tablets, e.g. prednisolone, beclomethasone).
- to treat certain bacterial infections (quinolone antibiotics, e.g. ciprofloxacin, norfloxacin, levofloxacin).
- that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- to stimulate your heart (e.g. glycosides) or medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan).
- to help you pass water (diuretics).
- for the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, tacrolimus).
- for mania or depression (e.g. lithium or SSRIs).
- for pregnancy termination (e.g. mifepristone).
- for HIV treatment (e.g. zidovudine).
- containing other sympathomimetic agents such as decongestants (e.g. pseudoephedrine).

Some other medicines may also affect or be affected by treatment of Care Cold & Flu Relief 200mg/5mg Film Coated Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Care Cold & Flu Relief 200mg/5mg Film Coated Tablets with other medicines.

Pregnancy, breast-feeding and fertility

Care Cold & Flu Relief 200mg/5mg Film Coated Tablets belongs to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking this medicine. It is unlikely that if you only take Care Cold & Flu Relief 200mg/5mg Film Coated Tablets occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

Tell your doctor if you become pregnant whilst taking Care Cold & Flu Relief 200mg/5mg Film Coated Tablets

Do not take this medicine in the last 3 months of pregnancy.

Avoid the use of this medicine in the first 6 months of pregnancy unless the doctor advises otherwise.

Talk to your doctor or pharmacist before taking this medicine if you are breast-feeding.

Sodium Content

This medicine contains less than 1 mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Care Cold & Flu Relief 200mg/5mg Film Coated Tablets

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

Method of administration

Tablets must be swallowed whole with water.

It is important to drink plenty of fluids when suffering from colds and flu.

Dosage

Adults, the elderly and children over 12 years:

Take two tablets every 8 hours. Leave at least 4 hours between doses and do not exceed 6 tablets in any 24 hour period.

Duration of treatment

- This medicine is for short-term use only.
- Take the lowest dose for the shortest time necessary.

Do not take Care Cold & Flu Relief 200mg/5mg Film Coated Tablets for longer than 10 days.

If you do not get better, or get worse, talk to your doctor. They will tell you if it is safe to carry on taking this medicine.

Do not give to children under 12 years.

If you take more Care Cold & Flu Relief 200mg/5mg Film Coated Tablets than you should:

If you have taken more of this medicine than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital immediately to get an opinion of the risk and advice on action to be taken, even if you feel well.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

If you forget to take Care Cold & Flu Relief 200mg/5mg Film Coated Tablets

Refer to the directions above on how to take this medicine and do not take more than is advised.

DO NOT take a double dose to make up for forgotten tablets.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. You may suffer one of the known side effects of NSAIDs (see below).

If you get any of the following at any time during your treatment **STOP TAKING, and get medical help straight away:**

- **signs of intestinal bleeding** such as:
 - pass blood in your stools or motions.
 - pass black tarry stools or motions.
 - vomit any blood or dark particles that look like coffee grounds.
- **signs of serious allergic reaction** such as:
 - difficulties in breathing or unexplained wheezing.
 - dizziness or faster heartbeat.
 - severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g. Stevens-Johnson syndrome).
 - swelling of your face, tongue or throat.
- **signs of kidney problems** such as:
 - passing less or more urine.
 - cloudy urine or blood in urine.
 - pain in the back and/or swelling (particularly in the legs).
- **signs of aseptic meningitis** such as:
 - neck stiffness.
 - headache.
 - feeling sick, being sick.
 - fever or disorientation. Patients with autoimmune disorders (Systemic Lupus Erythematosus, mixed connective-tissue disease) may be more likely to be affected.
- **signs of blood disorder** resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion.
- **signs of liver problems** such as stomach pain, nausea, jaundice (yellowing of the skin and the whites of the eyes) or passing dark brown urine.

STOP TAKING this medicine and tell your doctor if you experience the following uncommon side effects which may affect up to 1 in 100 people:

- indigestion or heartburn.
- pains in your stomach (abdomen) or other abnormal stomach problems.

TELL YOUR DOCTOR if you have any of the following side effects, they become worse or you notice any effects not listed:

Uncommon side effects which may affect up to 1 in 100 people:

- allergic reactions, such as skin rashes (urticaria), itching, peeling.
- headaches, dizziness, tinnitus (ringing in the ears).

Rare side effects which may affect up to 1 in 1,000 people:

- flatulence (wind), diarrhoea, constipation and vomiting.

Very rare side effects which may affect up to 1 in 10,000 people:

- blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion.
- drop in blood pressure or irregular heart beat.
- liver problems.

Side effects for which the frequency cannot be estimated from the available data:

- worsening of asthma or bronchospasm.
- swelling (oedema), high blood pressure, heart failure or attack.
- worsening of colitis and Chron's disease.
- difficulties in passing urine (in men only).
- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Care Cold & Flu Relief 200mg/5mg Film Coated Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

Medicines such as Care Cold & Flu Relief 200mg/5mg Film Coated Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. See section 2 "Warnings and precautions".

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

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

5. How to store Care Cold & Flu Relief 200mg/5mg Film Coated Tablets

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

Do not use this medicine after the expiry date (EXP month/year) which is stated on the pack.

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

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. 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 Care Cold & Flu Relief 200mg/5mg Film Coated Tablets contains

The active substances are:

- ibuprofen
- phenylephrine hydrochloride

Each film-coated tablet contains:

- 200mg ibuprofen
- 5mg phenylephrine hydrochloride

The other ingredients are:

The core consists of:

- microcrystalline cellulose
- sodium starch glycolate
- hypromellose
- sodium stearyl fumarate
- purified water

The film consists of:

- polyvinyl alcohol
- talc
- macrogol
- titanium dioxide
- methacrylic acid copolymer
- sodium bicarbonate
- purified water.

What Care Cold & Flu Relief 200mg/5mg Film Coated Tablets looks like and contents of the pack

Care Cold & Flu Relief 200mg/5mg Film Coated Tablets are white, round, biconvex, film-coated tablets with a score line on one side. The score line is not intended for breaking the tablet.

The product is available in cartons of 12 and 16 tablets.

Marketing Authorisation Holder

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