

Patient Information Leaflet
Coldease capsules
Paracetamol 400mg, Caffeine30mg, Chlorpheniramine Maleate 4mg
and Pseudoephedrine hydrochloride30mg

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 any side effects, talk to your doctor or pharmacist.
- This includes any possible side effects not listed in this leaflet. See section d.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

- a. What is Coldease capsules and what it is used for
- b. What you need to know before you take Coldease capsules
- c. How to take Coldease capsules
- d. Possible side effects
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a. What is Coldease capsules and what it is used for

Coldease capsules is used to relief of nasal congestion when combined with fever and/or pain such as sore throat, sinus pain or headache in the common cold or flu in adults and in children and adolescents aged 12 years and over. This medicine contains the active substances Paracetamol, Caffeine, Chlorpheniramine maleate and Pseudoephedrine hydrochloride.

Paracetamol which is a painkiller and reduces your temperature, Caffeine is the most active xanthine derivative in respect of stimulation of the central nervous system, producing a condition of wakefulness and increased mental activity. It is indicated for symptomatic relief of fever, headache, nasal congestion & rhinitis, associated with influenza and common cold. Chlorphenamine maleate is a potent antihistamine (H1-antagonist) it also has anticholinergic activity. Pseudoephedrine hydrochloride which is a decongestant which unblocks your nose and sinuses helping you breathe more easily without drowsiness.

b. What you need to know before you take Coldease capsules

Do not take this medicine:

- if you are allergic to paracetamol, pseudoephedrine hydrochloride or other sympathomimetics (such as decongestants, appetite suppressants or stimulant drugs called amphetamines), or any of the other ingredients of this medicine (listed in section f);
- if you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication
- if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure
- If you have overactive thyroid gland, enlarged prostate, heart problems, glaucoma (excessive pressure inside your eyes);
- if you have diabetes;
- if you have pheochromocytoma (a tumor near the kidney);
- if you have kidney problems, unless your doctor tells you to;
- if you have taken monoamine oxidase inhibitors (MAOIs), usually prescribed for depression, in the last two weeks;
- if you are taking the drug moclobemide for depression, beta-blockers for high blood pressure, the antibiotics furazolidone or linezolid, appetite suppressants, or stimulant drugs called amphetamines (sometimes used to treat attention deficit disorders or excessive sleepiness);
- with any other paracetamol containing products;
- with any other flu, cold or decongestant product;
- for more than 5 days unless your doctor tells you to;
- if you are under 12 years old.

Warnings and precautions

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section d "Possible side effects" for symptoms).

Talk to your doctor or pharmacist before taking this medicine:

- if you are due to undergo general anesthesia;
- if you have irregular heartbeat;
- if you have chronic alcoholism;
- if you have kidney or liver problems;
- if you have Gilbert's Syndrome (familial non-haemolytic jaundice);
- if you are taking other medicines that can affect the liver;
- if you are dehydrated;
- if you have had poor diet such that the diet causes health problems;

- if you weigh less than 50kg;
- if you are elderly;
- if you have glucose-6-phosphate dehydrogenase deficiency;
- if you have haemolytic anaemia;
- if you have frequent or daily headaches;
- if you have asthma and sensitivity to acetylsalicylic acid. They may reduce the dose or increase the time interval between doses of your medicine. Reduction of blood flow to your optic nerve may occur with this medicine.
- If you develop sudden loss of vision, stop taking this medicine and contact your doctor or seek medical attention immediately. See section d.

Other medicines and Coldease capsules

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

- anticoagulants (used to thin the blood, e.g. warfarin);
- metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]);
- cholestyramine (to lower blood cholesterol);
- medicines for high blood pressure;
- medicines for depression (tricyclic antidepressants);
- sodium bicarbonate (used to treat indigestion and certain kidney conditions);
- probenecid (used to treat gout and reduce uric acid);
- chloramphenicol (antibiotic);
- anticonvulsants or other medicines used to treat epilepsy (such as barbiturates);
- oral contraceptive steroids.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment, and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

One of the active ingredients in Coldease capsules, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Panadol Cold & Sinus than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section c).

Pregnancy and breastfeeding:

Do not take this medicine if you are pregnant or breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines: This product can cause dizziness as a side effect which could affect your ability to drive or use machines. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

c. How to take Coldease 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.

The recommended dose is: Adults (including the elderly) and children aged 16 and over:

- 2 capsules up to 3 times daily, every 4 hours as needed.
- Do not take more than 8 capsules in 24 hours.
- Elderly patients, especially those who are frail or immobile, may require a reduced dose or frequency of dosing.

Children aged 12 to 15 years:

- 1 capsule every 4-6 hours as needed.
- Do not give more than 3 capsules in 24 hours. For oral use. The capsules should be taken with water.
- Do not take more frequently than every 4 hours. Do not take for more than 3 days.
- Do not take more than the recommended daily dose.

If you take more Coldease capsules than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Liver damage may become apparent 12 to 48 hours after ingestion. Cardiac arrhythmias and pancreatitis have been reported. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

d. Possible side effects

Like all medicines, this medicine can have side effects, but not everybody gets them:

- serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) (frequency not known) Stop using Panadol Cold & Sinus immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

These include:

- severe headache with a sudden onset
- feeling sick
- vomiting
- confusion
- seizures changes in vision

Stop taking this medicine and seek immediate medical attention if you experience:

- Sudden severe headache. This is very rare (occurring in fewer than 1 in every 10,000 patients treated);
- Allergic reactions such as skin rash or itching, sometimes with breathing problems (or a hissing sound when you breathe) or swelling of the lips, tongue, throat or face. These reactions are rare (occurring in fewer than 1 in every 1,000 patients treated);
- Breathing problems, especially if you have experienced a similar reaction with aspirin or nonsteroidal anti-inflammatories. These are very rare (occurring in fewer than 1 in 10,000 patients treated);
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy) (frequency Not known).
- Serious skin reactions, skin rash or peeling, or mouth ulcers. These effects are very rare (occurring in fewer than 1 in 10,000 patients treated);
- Unexplained bruising or bleeding, or infections such as sore throat - this may be a sign of very rare changes in the blood. These occur in fewer than 1 in 10,000 patients treated;
- Difficulty and pain in passing urine. This is uncommon (occurring in fewer than 1 in every 100 patients treated) and is more likely to occur if you have an enlarged prostate gland. The following side effects may occur. Tell your doctor or pharmacist if you get them.
- Nausea [feeling sick], vomiting [being sick], dry mouth, sleep disturbance, nervousness and dizziness. These are common side effects, (occurring in fewer than 1 in every 10 patients treated);
- Rapid or irregular heart rate, agitation and restlessness. These are uncommon side effects (occurring in fewer than 1 in every 100 patients treated);
- High blood pressure and hallucinations are rare side effects (occurring in fewer than 1 in every 1,000 patients treated);
- Small bumps on your skin full of fluid or pus (pustules);
- Diarrhea with blood and mucus, abdominal pain and fever. This product may have side effects that you would not notice yourself. These include changes in some liver test results. If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

e. How to store Coldease capsules

- Do not store above 30°C
- Protect from light
- Keep out of reach of children
- Do not take this medicine after the expiry date which is stated on the blister and outer carton.
- The expiry date refers to the last day of that month
- Do not use this medicine if you notice the capsules are soft
- 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

f. Further information

What this medicine contains

Each capsule contains Paracetamol BP 400mg, Caffeine Anhydrous BP 30mg, Chlorpheniramine Maleate BP 4mg, Pseudoephedrine Hydrochloride BP 30mg.

The other ingredients are Colloidal silicone dioxide, Purified talc, Maize starch.

What this medicine looks like and contents of the pack

Pink coloured cap/pink coloured body '0' size capsule 'COLDEASE' imprinted on body and 'Rene Rene' imprinted on cap with black ink contains with off white colour powder.

Aluminium/ transparent PVC blister of 10 capsules and 10 of such blisters are packed in a unit box with pack insert.

MANUFACTURED BY

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A milestone to Golden Health