

Cold-Med®

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about Cold-Med

Each COLD-MED capsule for oral administration contains:

Paracetamol	300 mg
Pseudoephedrine HCl	30 mg
Pyrilamine maleate	15 mg
Noscapine	10 mg
Caffeine anhydrous	30 mg

Excipients are: corn starch and colloidal silicone dioxide.

Each 5 mL of Cold-Med syrup for oral administration contains:

Paracetamol	120 mg
Pseudoephedrine HCl	15 mg
Pyrilamine maleate	6.25 mg
Glyceryl guaiacolate (guaifenesin)	15 mg

Excipients are: sucrose, methylparaben, propylparaben, strawberry flavor, and purified water.

Cold-Med capsules contain a clinically proven analgesic-antipyretic, a decongestant, an antihistamine, a cough suppressant and a stimulant.

Cold-Med syrup contains a clinically proven analgesic-antipyretic, a decongestant, an antihistamine and an expectorant.

- Paracetamol produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulating center.
- Pseudoephedrine is a sympathomimetic amine which provides temporary relief of nasal congestion.
- Noscapine is a cough suppressant which provides temporary relief of cough due to minor throat irritations that may occur with common cold.
- Pyrilamine maleate is an antihistamine which helps provide temporary relief of runny nose, sneezing and watery and itchy eyes
- Caffeine is a central nervous system stimulant that counteracts the sedative effect that may eventually occur with the antihistamine.
- Glyceryl guaiacolate is an expectorant that loosens and thins sputum and bronchial secretions and eases expectoration.

Cold-Med provides effective control of the most common symptoms of common cold, influenza, bronchitis, laryngitis, and related conditions:

- Cough, sore throat, minor aches and pains, headache, fever
- Nasal congestion, runny nose, sneezing, watery and itchy eyes

The way to take Cold-Med

Use as directed. The usual recommended dosages are:

Age	Dose of Cold-Med capsules	Dose of Cold-Med syrup
Adults and children 12 years of age and older	1 or 2 capsules, 3 to 4 times per day, after meals.	10 to 20 mL 3 to 4 times per day after meals
Children 6 to 12 years		10 mL 3 to 4 times per day after meals

Children 1 to 5 years		5 mL 3 to 4 times per day after meals
Children 3 months to 1 year		2.5 mL 3 to 4 times per day after meals

Duration of treatment

The duration of treatment should not exceed 7 days unless directed by your doctor.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following cases:

- history of hypersensitivity to any of the components
- liver failure
- risk of angle-closure glaucoma
- severe coronary artery disease
- severe hypertension
- history of convulsions
- co-administration with MAOI

Precautions

- Consult a pediatrician before using for children younger than 2 years of age.
- Caution should be used when this drug is administered for elderly patients who are more predisposed to orthostatic hypotension, dizziness, sedation, chronic constipation and prostatic hypertrophy.
- Ask your doctor before using this product if you have heart disease, glaucoma, diabetes, hypertension, thyroid disease, liver or renal failure, trouble urinating due to an enlarged prostate gland, cough that occurs with too much phlegm (mucus), or if you have a breathing problem or chronic cough that lasts as occurs with smoking, asthma, chronic bronchitis, or emphysema.
- Stop use and ask a doctor if pain, nasal congestion, or cough gets worse or lasts for more than 7 days; if fever gets worse or lasts for more than 3 days; if redness or swelling is present, if new symptoms occur, if you get nervous, dizzy or sleepless, or if cough comes back or occurs with rash or headache that lasts.
- Consult your doctor if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting.
- Caution should be taken when driving a car or operating machinery since drowsiness may occur.
- Ask your doctor before use in case of pregnancy or lactation. Administration during pregnancy or lactation is not recommended.

Associations with other medications

Please inform your doctor or pharmacist if other medicines are being taken or have been taken recently.

Do not use this medicine if you are taking a monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions or Parkinson's disease), or for 2 weeks after stopping the MAOI drug.

This product contains paracetamol; therefore you should not take other drugs containing paracetamol to avoid the risk of overdose.

Avoid drinking excessive amounts of alcoholic beverages during treatment.

Ask your doctor or pharmacist before use if you are taking sedatives, tranquilizers, antidepressants, antipsychotics, or atropine derivatives.

Ciprofloxacin, norfloxacin, and cimetidine may increase blood concentrations of caffeine.

Adverse reactions

This drug is usually well tolerated when used as directed.

The most reported adverse reactions include sleep disturbances, dry mouth, anxiety, palpitations, restlessness, sweating.

Rarely reported adverse reactions include hallucinations, rash, nausea, vomiting, constipation, dizziness, urinary retention, and allergic reactions.

Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

Cold-Med capsules, pack of 16 capsules

Cold-Med syrup, bottle of 90 mL

Issue date: 08/2016

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