

REVAGRIP COMPLETE Capsules



Composition:

Each REVAGRIP COMPLETE Capsule contains:

Paracetamol 500 mg.

Guaifenesin 100 mg.

Phenylephrine hydrochloride 6.1 mg.

Pharmacological Properties & Mechanism of Action:

REVAGRIP COMPLETE consists of a special combination of drugs that combine:

Paracetamol: An effective analgesic and antipyretic, it works by inhibiting the synthesis of prostaglandins in the central nervous system.

Guaifenesin: An expectorant that increases sputum volume and reduces its viscosity.

Phenylephrine hydrochloride: A postsynaptic alpha receptor agonist, it has a decongestant effect by constricting blood vessels to reduce edema and swelling in the nose which helps breathing easier.

Pharmacokinetics:

Paracetamol: Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract, reaching peak plasma concentrations approximately 20 minutes after oral administration, rapidly distributing widely in most tissues of the body, metabolized mainly through the first hepatic pass and excreted in the urine in the form of glucuronic and sulfate-related compounds.

Guaifenesin: Guaifenesin is absorbed from the gastrointestinal tract and excreted in the urine after undergoing metabolism.

Phenylephrine hydrochloride: Phenylephrine hydrochloride is irregularly absorbed from the gastrointestinal tract, undergoes first-pass metabolism in both the gut and liver, reducing its bio-availability when given orally, and is almost completely excreted in the urine.

Indications:

REVAGRIP COMPLETE Capsule is used to relieve symptoms associated with the common colds and influenza, including relief from congestion and pain from sinusitis, sore throat and headache. REVAGRIP COMPLETE also helps lower fever, reduce mucus viscosity and soothe chesty coughs.

Contraindications:

REVAGRIP COMPLETE Capsules are contraindicated in the following cases:

- Hypersensitivity to the active material or to any of the components of the product.

- Concomitant use with other sympathomimetic decongestants.
- People with closed angle glaucoma.
- People with severe coronary heart diseases, cardiovascular disorders, high blood pressure.
- People with hyperthyroidism.
- People with severe hepatic or renal insufficiency
- Patients are taking tricyclic antidepressants or beta-blockers, and patients taking, or have taken within the last two weeks, monoamine oxidase inhibitors (MAOIs).

Warnings & Precautions:

- Avoid concomitant use with other paracetamol-containing products to avoid paracetamol overdose.

- A doctor should be consulted before using REVAGRIP COMPLETE Capsules in patients with: Chronic cough or asthma, obstructive vascular diseases (such as Raynaud's phenomenon), diabetes mellitus, phenylketonuria, severe gastrointestinal disturbances.

- Avoid concomitant use with cough suppressants.

- People with an enlarged prostate should consult a doctor before using this medicine.

Pregnancy & Lactation:

Pregnancy: The safety of this medicine during pregnancy has not been established, so REVAGRIP COMPLETE Capsules should not be used during pregnancy without consulting a doctor.

Lactation: REVAGRIP COMPLETE Capsules should not be taken while breast-feeding without consulting your doctor.

Drug Interactions:

Paracetamol: The anticoagulant effect of warfarin and other coumarin derivatives may be enhanced by regular and prolonged use of paracetamol with an increased risk of bleeding. The hepatotoxicity of paracetamol may be increased when it is taken with alcohol. The rate of absorption of paracetamol may be increased when co administered with metoclopramide or domperidone, while the rate of absorption is decreased when co administered with colestyramine.

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis, especially in patients with risks factors.

Phenylephrine: Concomitant use with monoamine oxidase inhibitors, other sympathomimetic amines, beta-blockers, other antihypertensive drugs, tricyclic antidepressants, ergot alkaloids, digoxin and cardiac glycosides may lead to hypertension and increased risk of cardiovascular and irregular heartbeat.

Guaifenesin: No interactions with other drugs have been observed.

Side Effects:

- Allergic reactions such as a skin rash, sometimes itching, with swelling of the mouth or face.
- Recurring fever or infection.
- Nausea, weight loss, loss of appetite.
- Arrhythmia.
- Hypertension.
- Difficulty urinating.
- Stomach upsets.
- Insomnia
- Nervousness, tremors.

Driving & Using Machines:

REVAGRIP COMPLETE Capsules may cause dizziness, you should avoid driving a car or operating machines while taking this medicine.

Dosage & Administration:

- Adults, the elderly and children 16 years of age and over: 2 capsules every 4-6 hours as needed.
- Do not take more than 8 capsules (4 doses) in 24 hours.
- Do not give to children under 16 years of age without consulting a doctor.
- You should consult a doctor or pharmacist if symptoms persist for more than 3 days.
- The capsules should be swallowed whole with water.

Overdose:

Symptoms: Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia, abdominal pain and liver damage. Effects of phenylephrine overdose include hypertension, cardiac arrhythmias, urinary retention, mydriasis, allergic reactions, closed-angle glaucoma and respiratory depression. Taking large doses of guaifenesin may cause nausea and vomiting.

Treatment: Patient should be referred to hospital urgently for immediate medical attention. Activated charcoal should be used if the overdose is taken within one hour. Treatment with N-acetylcysteine can be used within 24 hours of taking paracetamol.

Storage:

Keep out of reach of children. Store below 25 °C.

Packing:

Each REVAGRIP COMPLETE Capsules carton box contains 20 Capsules in two blister strips.

