Product Information

Summary of Product Characteristics (SmPC)

1. Name of the medical product

Dextromethorphan Hydrobromide 10mg+ Phenylephrine Hydrochloride 5mg + Doxylamine Succinate 6.25mg+ Acetaminophen 325mg caplet

2. Qualitative and quantitative composition

Each caplet contains:
Dextromethorphan Hydrobromide 10mg
Phenylephrine Hydrochloride 5mg
Doxylamine Succinate 6.25mg
Acetaminophen 325mg

3. Pharmaceutical form

Caplet

4. Clinical particulars

4.1 Indications

for the temporary relief of the following cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough

helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
temporarily reduces fever

4.2 Dosage and administration

Adults: Take 1 caplet before bed time
Children: Not recommended for children below 12years

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

4.3 Contraindications

Hypersensitivity to any of the ingredients. Avoid in patients with cardiovascular disease, hypertension, diabetes, hyperthyroidism, phaeochromocytoma, closed angle glaucoma, prostatic enlargement and liver failure.
Patients being treated with monoamine oxidase inhibitors, or within 14 days of ceasing such treatment.

4.4 Warnings and precautions

Liver warning
This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours.
Severe liver damage may occur if you take
- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen

- 3 or more alcoholic drinks every day while using this product

Sore throat warning
If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription 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. If you do not know if your contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

4.5 Interaction with other drugs
If you are now taking a prescription 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. If you do not know if your contains an MAOI, ask a doctor or pharmacist before taking this product.

4.6 Adverse Effects:
- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

5. Pharmacological properties
5.1 Pharmacodynamic properties
Acetaminophen is a peripherally acting analgesic with antipyretic properties.
Phenylephrine is a sympathomimetic agent with predominantly alpha adrenergic activity. It has decongestant and weak bronchodilator activity.

5.2 Pharmacokinetic properties
Acetaminophen is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10-60 minutes after oral administration. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk.
Plasma protein binding is negligible at usual therapeutic concentrations.
Acetaminophen is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates.
Less than 5% is excreted as unchanged paracetamol. Elimination half life varies from about 1 to 3 hours.
Phenylephrine has low oral bioavailability owing to irregular absorption and first pass metabolism by monoamine oxidase in the gut and liver. Peak plasma concentrations are achieved within 1-2 hours. The mean plasma half life is in the range 2-3 hours.

6. Pharmaceutical properties
6.1 List of excipients
Microcrystalline cellulose, Starch, Talc, Magnesium Stearate.

6.2 Incompatibilities

None known.

6.3 Shelf life
3 years

6.4 Storage
Store in a cool place and air tight container
KEEP MEDICINES OUT OF REACH OF CHILDREN