

Product Name: VIXA Night Cold-Flu & Allergy Softgel capsules (Dextromethorphan hydrobromide 10mg+Phenylephrine HCl 5mg+Doxylamine Succinate 6.25mg+Acetaminophen 325mg softgel capsules)

Product Information

Summary of Product Characteristics (SmPC)

1. Name of the medical product

Dextromethorphan hydrobromide 10mg+Phenylephrine HCl 5mg+Doxylamine Succinate 6.25mg+Acetaminophen 325mg softgel capsules

2. Qualitative and quantitative composition

Each capsule contains:

Dextromethorphan Hydrobromide 10mg

Phenylephrine Hydrochloride 5mg

Doxylamine Succinate 6.25mg

Acetaminophen 325mg

3. Pharmaceutical form

Capsule

4. Clinical particulars

4.1 Indications

temporarily relieves these symptoms due to a cold or flu:

- minor aches and pains
- headache
- nasal and sinus congestion
- cough
- sore throat
- runny nose

temporarily reduces fever

4.2 Dosage and administration

do not take more than the recommended dose

adults and children 12 years of age and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.

children under 12 years of age: do not use

4.3 Contraindications

Ask a doctor before use if you have liver disease, heart disease, high blood pressure, thyroid disease, diabetes, glaucoma, cough with excessive phlegm (mucus), a breathing problem such as emphysema or chronic bronchitis, difficulty in urination due to enlargement of the prostate gland, persistent or chronic cough such as occurs with smoking, asthma, or emphysema

4.4 Warnings and precautions

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 10 softgels in 24 hours, which is the maximum daily amount for this product
- 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 to sedate children.

4.5 Interaction with other drugs

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

4.6 Adverse Effects:

pain, cough, or nasal congestion gets worse or lasts more than 7 days

fever gets worse or lasts more than 3 days

redness or swelling is present

new symptoms occur

cough comes back or occurs with rash or headache that lasts.

nervousness, dizziness, or sleeplessness occurs

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

Polyethylene Glycol 400, Propylene Glycol, Povidone.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years

6.4 Storage

Store in a cool place and air tight container

KEEP MEDICINES OUT OF REACH OF CHILDREN