

PACKAGE INSERT

DEXCOPHAN TABLET

VIDEX00-M

Description

Round, white film-coated tablet, bevel-edged, flat-faces; "HD" and break-bar embossed on the same face.

Composition

Each film-coated tablet contains Dextromethorphan HBr 15 mg.

Actions and Pharmacology

Dextromethorphan suppresses the cough reflex on the cough centre but has no other depressant action on the central nervous system. Oral absorption is rapid; and it undergoes first pass hepatic metabolism and renal excretion.

Pharmacokinetics

Absorption

Dextromethorphan is fully absorbed from the gastrointestinal tract.

Blood Concentration

After an oral dose of 30mg of dextromethorphan HBr, 10, 25 and 10% of the dose was detected in the blood at 1, 2.5 and 6 hours respectively after administration.

Nevertheless plasma levels of unmetabolised dextromethorphan following the administration of therapeutic oral doses are very low due to extensive metabolism in the liver (first pass effect) and distribution which remove the drug rapidly from the blood.

Metabolism

After oral administration, dextromethorphan is absorbed from the intestinal tract and passes via the portal vein to the liver before entering the general circulation.

In the liver it is metabolised (first pass effect) to an extent which is large but which varies widely between individuals. Three metabolites have been identified in man. All three metabolites have approximately the same antitussive potency as dextromethorphan in guinea pigs.

There is a wide variation between individuals in the large first pass effect. Therefore, the proportions of dextromethorphan that are O-demethylated and N-demethylated vary widely between individuals. After O- or N-demethylation, the metabolites undergo glucuronic acid or sulphate conjugation.

Excretion

Up to 56% of a dose is excreted in the urine, about 8% being excreted unchanged in 6 hours. However there is a wide variation in the reported excretion of dextromethorphan and its metabolites. This reflects the large intersubject differences in the first pass effect.

Indications

Dextromethorphan is a cough suppressant used in the treatment of unproductive cough.

Contraindications

Contraindicated in patients hypersensitive to propylene glycol.

Precautions

- Caution in patients with asthma and hepatic function impairment.
- Safety for use in pregnancy and lactation has not been established.

Main Side/Adverse Effects

Drowsiness, dizziness, gastrointestinal disturbances, mental confusion.

Drug Interactions

Concurrent use with monoamine oxidase (MAO) inhibitors is not recommended since it may result in CNS depression.

Overdose

Clinical features: Nausea, vomiting, abdominal discomfort, hallucinations, hypotension, ataxia, respiratory depression.

Treat overdose by emesis or gastric lavage, if appropriate.

Administer naloxone 0.4 - 1.2 mg IV or IM in an adult or 5 - 10 µg per kg body weight IV or IM in children, repeated as necessary.

Dosage and administration

Adults

15 to 30 mg every four hours as needed; up to 120 mg per day.

Children

7 to 12 years of age: 7.5 mg to 15 mg every four hours as needed; up to 60 mg per day.

Note: The information given here is limited. For further information consult your doctor or pharmacist.

Storage

: Store below 30°C. Protect from light.

Presentation/Packing

: Film-coated tablet 15 mg x 1000's, Blisters of 100 x 10's, 10 x 10's.

Marketing authorization holder

: HOVID Bhd., 121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia.

Manufactured by

: HOVID Bhd., Lot 56442, 7 1/2 Miles, Jalan Ipoh / Chemor, 31200 Chemor, Malaysia.

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