8027463-805

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

IBSCIM

(CIMETROPIUM BROMIDE 50MG TABLET)

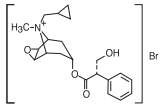
DESCRIPTION:

Each uncoated tablet contains :

Cimetropium Bromide 50 mg

Chemical Name: Hyoscine-N-(cyclopropylmethyl) Bromide,9-Cyclopropylmethyl-7-(3-hydroxy-2-phenyl propionyloxy)-9-methyl-3-oxa-9-azonia-tricyclo[3.3.1.02,4] nonane bromide.

Its molecular formula is C_{21}-H_{28}-Br-N-O_4 and its molecular weight is 438.4. The structural formula is:



INDICATIONS

Cimetropium tablets are indicated for the treatment of irritable bowel syndrome.

DOSAGE AND ADMINISTRATION

ADULT DOSAGE

Disorder of gastrointestinal tract

For treatment of functional diseases involving conditions of the digestive tract, such as gastrointestinal spasm and irritable bowel syndrome, the adult oral dose is 50 milligrams two to three times daily. It may also be given via rectal suppository.

CONTRAINDICATIONS

Cimetropium is contraindicated in individuals with a known hypersensitivity reaction to the product. It is also contraindicated in prostatic enlargement, paralytic ileus or pyloric stenosis.

WARNINGS AND PRECAUTIONS

Caution when used in patients with diarrhoea or fever, thyrotoxicosis, heart failure and in cardiac surgery.

Not advisable for use in

- Glaucoma.
- Prostatic hyperplasia
- Urinary retention
- Reflux esophagitis
- Intestinal obstruction
- Chronic airway obstruction
- Congestive heart failure
- Cardiac arrhythmias

DRUG INTERACTIONS

Effects may be enhanced when used with drugs with antimuscarinic properties e.g. amantadine, some antihistamines, phenothiazines and TCAs. May antagonise the GI effects of cisapride, domperidone and metoclopramide.

UNDESIRABLE EFFECTS

Adverse drug reactions include mouth dryness, reduced bronchial secretions, pupil dilatation with loss of accommodation and photophobia, skin flushing and dryness, mild transient hypertension, transient bradycardia followed by tachycardia, with palpitations and arrhythmias, blurred vision and micturition difficulty, as well as reduction in tone and motility of the GI tract resulting in constipation. Central nervous system effects due to cimetropium are absent or mild. sleepiness and, rarely, dizziness have been reported.

CLINICAL PHARMACOLOGY

Pharmacodynamic

Mechanism of Action

Cimetropium bromide is a quaternary ammonium semisynthetic derivative of the belladonna alkaloid scopolamine. Cimetropium bromide is an antimuscarinic with peripheral effects similar to those of atropine. Cimetropium interact with muscarinic receptors behave as a competitive antagonist of muscarinic receptor-mediated contractions. Cimetropium is potent inhibitor of large bowel motility evoked by endogenous stimuli and neostigmine and it mainly distributed in colonic tissues.

Pharmacokinetics

Absorption and Bioavailability

Cimetropium bromide is a quaternary ammonium antispasmodic drug, which was assessed after intravenous and oral administration to healthy subjects. The concentration-time profile showed multiple peaking, which was attributed to two distinct absorption phases. The absorption was poor and discontinuous, and abruptly ended during the second phase. It is thought that the low concentrations (1-4% of the administered dose) that are absorbed are able to still produce therapeutic effects, and that there is accumulation sites along the gastrointestinal tract, which may lead to multiple peaks that can account for the interesting concentration-time profile of cimetropium bromide. Total absorption ranged from 1.4% to 4.1%. Time to reach Peak Concentration is 1.7 hours. The maximum plasma levels ranged from 18 to 38 ng/mL.

Distribution

The calculated half-life of the distribution phase was 5 minutes, with a terminal elimination half-life of 50 min. The fraction of the drug in the central compartment was estimated to be 0.29, indicating that approximately one-third of the drug in the body is available for elimination.

Metabolism and Elimination

After intravenous administration of 10 mg cimetropium bromide, plasma levels of the parent compound showed biexponential decay. Urinary excretion was 46% of the administered dose. After intravenous administration, the plasma levels and urinary excretion indicated that the drug is distributed and eliminated at a rapid rate (terminal half-life, 50 ± 8 min) and that urinary excretion is not the exclusive route of elimination (46 ± 2%) of the administered dose. Elimination Half-life of Cimetropium is 50 minutes. After oral dosing in healthy male volunteers, urinary excretion recovery (0 to 48 hours) ranged from 0.1% to 0.6%.

Other Excretion: The excretion of drug into the bile is around 7.5%.

EXPIRY DATE

Do not use later than the date of expiry.

STORAGE

Store at a temperature not exceeding 30ºC, protected from light and moisture.

Keep out of reach of children

PRESENTATION

IBSCIM is available in blister strip pack of 10 tablets.

torrent

Manufactured by:
TORRENT PHARMACEUTICALS LTD.
Vill.Bhud & Makhnu Majra, Baddi-173 205,
Teh. Nalagarh, Dist. Solan (H.P.), INDIA.