size: 2.7 x 9.0 inch

BRONCHOWIN

POM

Doxofylline Tablets / Syrup

Doxofylline Tablets
Each film coated tablet contains:
Doxofylline…….400 mg

Doxofylline Syrup
Each 5 ml contains:
Doxofylline…….100 mg

DESCRIPTION

Bronchowin contains Doxofylline which is a novel bronchodilator xanthine that differs from theophylline by the presence of dioxlane group in position 7. Like theophylline, Doxofylline's mechanism of action is related to the inihibition of phosphodiasterase activities. However, differently from theophylline, Doxofylline appears to have decreased affinities towards adenosine A1 and A2 receptors which may account for the better safety profile of the drug.Doxofylline is chemically designated as 7 (1,9 dioxalane -2-yimethyl) theophylline, its molecular formula is $C_{11}H_{14}N_4O_4$ and its molecular weight is 266.26.

PHARMACODYNAMICS

Bronchodilating activities of Doxofylline have been demonstrated in clinical trials involving patients with either bronchial astimate of chronic obstructive pulmonary disease (COPD). Doxofylline was found to be particularly effective in both decreasing the daily asthma attack rate as well as the beta-2- against consumption. The safety profile shows a better tolerability on cardiovascular, digestive and the CNS systems. No relationship has been reported between Doxofylline serum levels and the occurrence of adverse events. Neither relevant alteration of sleep architecture noncardiac chronotropic actions nor gastric secretion stimulation has been reported in clinical trials.

PHARMACOKINETICS

The half-life of Doxofylline is greater than six hours: so as to allow effective constant plasma levels with a t.i.d dose regimen. Single dose pharmacokinetic studies in man alter oral and intravenous administration defined distribution and absorption of the drug. After administration of 100 mg to 5 healthy volunteers, distribution of doxofylline in plasma followed a bicompartmental model during the distribution phase the plasma AUC was only a modest portion of the total AUC; plasma clearance was somewhat high ranging from 444 ml/min to 805 ml/min: apparent volume of distribution was about 1 kg. The mean half-life after i.e. administration was about 65 min (from 40 min to 96 min). After oral administration, peak plasma levels were reached after one hour. Absolute bioavailability is about 62.6 % at a pH 7.4 plasma protein binding of the compound is about 48% less than 4 % less than 4 % of an orally administration dose is excreted unchanged in the urine. Doxofylline is almost completely metabolized in the liver (90 % of the total drug clearance). Hydroxyethyl theophylline is the only detectable circulating metabolic of Doxofylline. After repeated administrations, Doxofylline reaches the steady state in about 4 days, the elimination half life during long term treatment is about 8-10 hours, and this allows a twice daily dose regimen. No accumulation of the drug was noted after one week of treatment.

INDICATIONS

BRONCHOWIN is indicated for the treatment of bronchial asthma and chronic obstructive pulmonary disease (COPD).

DOSAGE AND METHOD OF ADMINISTRATION

BRONCHOWIN tablets should be taken as one tablet (400 mg) two times a day. The dosage may be increased to t.i.d. according to the prescribing physician.

Pediatrics the recommended dosage of Doxofylline is 12 mg/ daily divided into 2 doses in case of unsatisfactory response, it can be increased upto 18 mg/kg daily under medical supervision.

CONTRAINDICATIONS

BRONCHOWIN is contraindicated in individuals who have shown hypersensitivity to its components. It is also contraindicated in patients with acute myocardial infarction, hypotension and in lactating women.

PRECAUTIONS & WARNINGS

Doxofylline should be used with caution in patients with hypertension, heart disease, hypoxemia, and hyperthyroidism, chronic right ventricular failure, congestive heart failure, liver failure, and liver disease, renal disease, in those with history of peptic ulcer and in elderly. Frequently, patients with congestive heart failure have markedly prolonged drug plasma level following discontinuation of the drug.

USAGE IN PREGNANCY & LACTATION

Animal reproduction studies indicate that Doxofylline does not cause total harm when administered to pregnant animals nor can affect reproduction capacity. However, since there is limited experience in human during pregnancy xanthenes should be given to pregnant women only if clearly needed.
Doxofylline is contraindicated in nursing mothers.

DRUG INTERACTIONS

Doxofylline should not be administered together with other xanthine derivatives. Toxic synergism with ephedrine has been documented for xanthines. Like other xanthines, concomitant therapy with erythromycin, troleandomycin, lincomycin, allopurinol, cimetidine, ranitidine, propranolol and anti flu-vaccine may decrease the hepatic clearance of xanthenes and cause an increase in level. However no evidence of relationship between Doxofylline serum concentrations and toxic events has been reported.

ADVERSE EFFECTS

After xanthine administration, nausea, vomiting epigastria pain cephaiagia (headache), irritability insomnia, bradycardias, extrasystole, tachypnea and occasionally hyperglycemia and albuminuria may occur if a potential oral overdose is established the patient may present with severe anthy and seizure; these symptoms could be the first sign of intoxication.

OVERDOSE

Although no major arrhythmias have been documented with Doxofylline, major cardiac rhythm disturbances cannot be excluded in case of over dosage of xanthine compounds. If a potential oral overdose is established, the patient may present with seizures, these symptoms could be the first sign of intoxication.
There is no specific antidote; it is suggested that the management principles should be in situtad according to a symptomatic relief of cardio circulatory shock. Doxofylline does not cause any risk of tolerance or addiction.

GERIATRICS

The dosage (9800mg/day) may be decreased according to medical prescription in the very patients with concomitant cardiovascular, hepatic. Renal and gastric, to half (1/2) tablet b.i.d

STORAGE

Store below 30°C. Protect from light & moisture.
KEEP THE MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION

Bronchowin Tablet: Three Alu-Alu strip of 10 Tablets
Bronchowin Syrup: 60 ml amber pet bottle.

Manufactured for & Distributed by:
medisel
(Kenya) Limited
P. O. Box 540, Thika, Kenya.

Manufactured in India by :
CORONA Remedies Pvt. Ltd.
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