Doxobron®

Doxofylline

COMPOSITION:
Doxobron ® 200 Tablet: Each film-coated tablet contains Doxofylline INN 200 mg.
Doxobron ® 400 Tablet: Each film-coated tablet contains Doxofylline INN 400 mg.
Doxobron ® Syrup: Each 5 ml syrup contains Doxofylline INN 100 mg.

PHARMACOLOGY:
Doxofylline is a newer xanthine derivative which differs from theophylline in containing the dioxolane group at position 7. As with theophylline, its mechanism of action is related to the inhibition of the phosphodiesterase enzymes, but it has been claimed to have decreased affinities towards the adenosine A_1 and A_2 receptors, which has been claimed as a reason for its better safety profile.

INDICATION:
Doxofylline is indicated for the treatment of bronchial asthma, Chronic Obstructive Pulmonary Disease (COPD) & Bronchospasm.

DOSE & ADMINISTRATION:
- Adult: 400 mg tablet one or two times daily or as prescribed by a physician. (Maximum-120 mg/day).
- Elderly: 200 mg tablet two or three times daily.
- Children: (Above 6 years of age)
  >12 years: 10 ml syrup or 200 mg tablet two times daily.
  <12 years: 6-9 mg/kg body weight two times daily.
  Doxofylline may be taken with or without food.

CONTRA-INDICATION:
Doxofylline is contraindicated in individuals who have shown hypersensitivity to the drug and its components. It is also contraindicated in patients with Acute MI, hypotension, arrhythmia, duodenal ulcer, epilepsy and convulsions.

WARNING AND PRECAUTION:
The half-life of xanthine derivatives influenced by a number of known variables. It may be prolonged in patients with liver disease, in patients with congestive heart failure, in those affected with chronic obstructive lung disease or concomitant infections and in those patients taking certain other drugs , erythromycin, troleandomycin, lincomycin and other antibiotics of the same group, allopurinol, cimetidine, propranolol, and anti-flu vaccine. In these cases, a lower dose of Doxofylline may be needed. Phenytoin, other anticonvulsants and smoking may cause an increase in clearance with a shorter mean half-life, in these cases higher doses of Doxofylline may be needed. Caution is advised for those patients with hypoxemia, hyperthyroidism, liver disease, renal disease, in those with history of peptic ulcer and in elderly. Frequently, patients with congestive heart failure have markedly prolonged drug serum levels following discontinuation of the drug.

SIDE EFFECTS:
After xanthine administration, nausea, vomiting, epigastric pain, cephalgia, irritability, insomnia, tachycardia and occasionally hyperglycemia and albuminuria, may occur.

USE IN PREGNANCY & LACTATION:
Animal reproduction studies indicate that Doxofylline does not cause fetal harm when administered to pregnant animals nor can affect reproduction capacity. However since there are limited experiences in humans during pregnancy, xanthines should be given to pregnant women only if clearly needed. Doxofylline is contraindicated in nursing mothers.

USE IN CHILDREN & ADOLESCENTS:
Doxofylline may be used cautiously in children and adolescents.

DRUG INTERACTION:
Doxofylline should not be administered together with other xanthine derivatives, including beverages and foods containing caffeine.Toxic synergism with ephedrine has been documented for xanthines. Concomitant therapy with erythromycin, troleandomycin, lincomycin, clindamycin, allopurinol, cimetidine, propranolol and anti-flu vaccine may decrease the hepatic clearance of xanthines causing an increase in blood levels.

OVERDOSE:
Although no major arrhythmias have been documented with Doxofylline tablets the occurrence of major cardiac rhythm disturbances cannot be excluded in case of overdosage 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. Adverse reactions may cause the withdrawal from treatment. There is no specific antidote. It is suggested that the management principle should be instituted according to a symptomatic relief. Doxofylline does not cause any risk of tolerance or addiction.

STORAGE:
Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:
Doxobron ® 200 Tablet: Each box containing 5x10's tablets in blister pack.
Doxobron ® 400 Tablet: Each box containing 5x10's tablets in blister pack.
Doxobron ® Syrup: Each bottle containing 100 ml syrup with a 10 ml measuring cup.

Manufactured by
Team Pharmaceuticals Ltd.
B 75-79, BSCIC, Rajshahi, Bangladesh

IST-0037