Flindof™

Doxofylline 200 & 400 mg

COMPOSITION
Flindof™ 200 tablet: Each film-coated tablet contains Doxofylline INN 200 mg
Flindof™ 400 tablet: Each film-coated tablet contains Doxofylline INN 400 mg

PHARMACOLOGY
Doxofylline 7- (1, 3 dioxolane-2-yl methyl) 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 A1 and A2 receptors, which has been claimed as a reason for its better safety profile.

INDICATION
Doxofylline is indicated for the treatment of bronchial asthma, pulmonary disease with spastic bronchial component and Chronic Obstructive Pulmonary Disease (COPD).

DOSAGE AND ADMINISTRATION
• Adults: 400 mg tablet two or three times daily or as prescribed by a physician.
• Elderly: 200 mg tablet two or three times daily
• Maximum Daily Dose: 1,200 mg.
• <12 yr: 6-9 mg/kg body wt bid.
Doxofylline may be taken with or without food.

ADVERSE EFFECTS
After xanthine administration, nausea, vomiting, epigastric pain, cephalalgia, irritability, insomnia, tachycardia, and occasionally hyperglycemia and albuminuria, may occur. If a potential oral overdose is established, the patient may present with severe arrhythmias and seizure; these symptoms could be the first sign of intoxication. Adverse reactions may cause the withdrawal from treatment; a lower dose rechallenge may start only after the advice of physician.

OVERDOSAGE
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. A lower dose re-challenge may start only after the advice of the physician. There is no specific antidote. It is suggested that the management principle should be instituted according to a symptomatic relief of cardio circulatory shock. Doxofylline tablets does not cause any risk of tolerance or addiction.

PRECAUTIONS
The half-life of xanthine derivatives is 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. Phenytoins, 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.

CONTRAINDICATIONS
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.

DRUG INTERACTIONS
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.

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.

STORAGE CONDITION
Store below 30°C. Protect from light and moisture.
Keep out of the reach of children.

HOW SUPPLIED
Flindof™ 200 Tablet: Each box containing 30 tablets in Alu-PVDC blister pack.
Flindof™ 400 Tablet: Each box containing 30 tablets in Alu-PVDC blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH