Doxolator

Doxofylline INN

Composition
Doxolator 200 mg Tablet: Each film coated tablet contains Doxofylline INN 200 mg.
Doxolator 400 mg Tablet: Each film coated tablet contains Doxofylline INN 400 mg.
Doxolator Syrup: Each 5ml syrup contains Doxofylline INN 100 mg.

Description
Doxofylline is a novel bronchodilator xanthine that differs from theophylline for the presence of a dioxolane group in position 7. Like theophylline, doxofylline's mechanism of action is related to the inhibition of phosphodiesterase activities. Moreover, doxofylline appears to have decreased affinities toward adenosine A_1 and A_2 receptors which may account for the better safety profile of the drug. Doxofylline also inhibits platelet activating factor and the generation of leukotrienes.

Indication
Doxolator (Doxofylline) is used to treat asthma, COPD & bronchospasm.

Dosage & Administration
Adult: 400 mg (1 tablet) daily in the evening. However, in certain cases, 400 mg twice daily is recommended on the basis of the clinical response. Doses as high as 1200 mg/day (400 mg 3 times daily) may also be prescribed. In elderly patients with concomitant cardiovascular, hepatic and renal diseases recommended dosage should be 200 mg twice daily.

Children (above 6 years of age): The recommended dosage of doxofylline is 6 mg/kg twice daily. The dose may be increased up to 18 mg/kg daily on the basis of clinical response.

Dosage	Weight of the children						
	10 kg	15 kg	20 kg	25 kg	30 kg	35 kg	40 kg
6 mg/kg b.i.d	3 ml	4.5 ml	6 ml	7.5 ml	9 ml	10.5 ml	12 ml
Total daily dose	6 ml	9 ml	12 ml	15 ml	18 ml	21 ml	24 ml

Side effects
After xanthine administration, nausea, vomiting, abdominal pain, epigastric distress, insomnia, headache, nervousness and dizziness may occur. Adverse cardiovascular effects include tachycardia, extrasystoles and palpitation, albuminuria and hyperglycemia may also occur.

Contraindications
Hypersensitivity to any excipients of doxofylline and its components or to other methylxanthines. It is also contraindicated in patients with acute myocardial infarction, hypertension and breastfeeding women.

Precautions
Xanthine clearance may be altered by different variables affecting its half-life ($t_{½}$). In patients with cardiovascular failure, renal or hepatic dysfunction, in those with COPD, in patients undergoing influenza immunization or who have an active influenza infection and in patients taking other drugs (eg. cimetidine, allopurinol, propranolol, erythromycin, troleandomycin, lincomycin and ciprofloxacin) clearance may be decreased and its $t_{½}$ increase. The dose of doxofylline may be reduced in these conditions. In patients who are taking phenytoin and other anticonvulsants and in those who are smoking, clearance may be increased and its $t_{½}$ decreased. In these cases, a higher dose of doxofylline may be required. Caution in patients with the following conditions: Peptic ulcer, hyperthyroidism, hypoxemia, renal or hepatic dysfunction, cardiovascular disorders including arrhythmias, angina pectoris, acute myocardial injury or hypertension and convulsive disorder.

Use in pregnancy
The safe use of doxofylline during pregnancy has not been established. Doxofylline should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in lactation
Methylxanthines are distributed into all body compartments. They cross the placenta and are distributed into breast milk. Doxofylline is contraindicated in breastfeeding mother.

Drug Interactions
Doxofylline should not be administered concomitantly with other methylxanthines, including beverages and food containing caffeine. Xanthine clearance may be decreased by interaction with cimetidine, allopurinol, propranolol, erythromycin, troleandomycin, lincomycin and anti-flu vaccine. Synergistic toxicity with ephedrine has also been reported for xanthines.

Storage
Store in a cool (below 30° C) and dry place, protect from light. Keep out of reach of children. Do not freeze.

Packaging
Doxolator 200 mg Tablet: Each box contains 5x10's tablets in blister pack.
Doxolator 400 mg Tablet: Each box contains 3x10's tablets in blister pack.
Doxolator Syrup: Each bottle contains 100 ml syrup.

Manufactured by

ZISKA PHARMA

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