

Dophylin™

Tablet & Syrup

Doxophylline INN

COMPOSITION**Dophylin™ 200 Tablet** : Each film-coated tablet contains Doxophylline INN 200 mg.**Dophylin™ 400 Tablet** : Each film-coated tablet contains Doxophylline INN 400 mg.**Dophylin™ Syrup** : Each 5 ml syrup contains Doxophylline INN 100 mg .**PHARMACOLOGY**

Dophylin™ (Doxophylline) is a novel bronchodilator. It structurally differs from Theophylline due to the presence of a dioxolane group in position 7. Doxophylline selectively inhibits phosphodiesterase-4 thereby relaxes bronchial smooth muscle. However, differently from Theophylline, Doxophylline appears to have decreased affinities toward adenosine A₁ and A₂ receptors, which may account for the better safety profile of the drug. Doxophylline is reported to inhibit platelet activating factor (PAF) and generation of leukotriene production.

INDICATION**Dophylin™** (Doxophylline) is used to treat Asthma, COPD and bronchospasm.**DOSAGE AND ADMINISTRATION****Route of administration** : Orally.**Dophylin™ 200 Tablet** : 1 tablet two times daily. On the basis of clinical response the dose may be increased to 2 tablet twice daily.**Dophylin™ 400 Tablet** : 1 tablet daily at night. On the basis of clinical response the dose may be increased to 1 tablet twice daily.**Dophylin™ Syrup** : 6 mg/kg twice daily for children above 6 years of age.**OR AS DIRECTED BY THE PHYSICIAN.****CONTRAINDICATIONS**

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

PRECAUTION

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 and in those patients taking certain other drugs like erythromycin, troleandomycin, lincomycin, allopurinol, cimetidine, propranolol and anti-flu vaccine. In these cases, a lower dose of Doxophylline 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 Doxophylline may be needed.

SIDE EFFECTS

Common side effects: Doxophylline rarely causes serious side effects, however possible side effect are similar for taking excess amount of caffeine. These include: nausea, vomiting, headaches, upset stomach and heartburn.

Rare side effects: Abdominal pain, Sweating, Irregular Pulse Rhythm, Precordial Pain

USE IN PREGNANCY AND LACTATION

Animal reproduction studies indicate that, Doxophylline does not cause fetal harm when administered to pregnant animals or can not affect reproduction capacity. However, since there is limited experience in human during pregnancy, xanthines should be given to pregnant women only if clearly needed. Doxophylline is contraindicated in nursing mothers.

USE IN CHILDREN & ADOLESCENTS

Doxophylline shows better efficacy in pediatric bronchial asthma, it shorten the duration of symptoms. Dosage recommended for children > 6 yrs of age is 6 mg/Kg/dose twice daily.

DRUG INTERACTION

With medicine : Doxophylline should not be administered together with other xanthine derivatives. Toxic synergism with ephedrine has been documented for xanthines. Like other xanthines, concomitant therapy with troleandomycin, lincomycin, clindamycin, allopurinol, cimetidine, ranitidine, propranolol and anti-flu vaccine may decrease the hepatic clearance of xanthines causing an increase in blood levels. No evidence of a relationship between Doxophylline serum concentrations and toxic events have been reported.

With food & others : There is no adequate data regarding the reaction with food and others.

OVERDOSE

Seizures may occur in case of overdose. If not occur, stomach should be emptied immediately by inducing emesis or by gastric lavage. If the patient is having seizures, an adequate airway should first be established and maintained. Seizures may be treated with intravenous diazepam, phenobarbital or in combination.

STORAGE

Store below 30° C temperature & dry place, protected from light.

Keep all medicines out of reach of the children.

PACKING**Dophylin™ 200 Tablet** : Each box contains 6x10 tablets in Alu-PVDC blisters.**Dophylin™ 400 Tablet** : Each box contains 3x10 tablets in Alu-PVDC blisters.**Dophylin™ Syrup** : Each bottle contains 100 ml syrup.***Further information is available on request**

Manufactured by:
The ACME Laboratories Ltd.
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 For Health, Vigour and Happiness