

COMPOSITION

Doxiva[®] 200 Tablet: Each film coated tablet contains Doxophylline INN 200 mg.

Doxiva[®] Tablet: Each film coated tablet contains Doxophylline INN 400 mg.

Doxiva[®] Syrup: Each 5 ml syrup contains Doxophylline INN 100 mg.

PHARMACOLOGY

Doxiva[®] (Doxophylline) is a noble 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

Doxiva[®] (Doxophylline) is used to treat asthma, COPD and bronchospasm.

DOSAGE AND ADMINISTRATION

Adults: 200 to 400 mg tablet two or three times daily or as prescribed by the physician.

Elderly: 200 mg tablet two or three times daily.

Children:

>6 years of age: 6-9 mg/kg body weight two times daily, i.e. if body weight is 10 kg, 3ml (60 mg) two times daily or as prescribed by the physician.

CONTRAINDICATION

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.

WARNING AND 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 EFFECT

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

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.

DRUG INTERACTION

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, 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.

STORAGE CONDITION

Tablet: Keep below 30°C temperature, protected from light and moisture.

Syrup: Keep below 30°C temperature in cool and dry place, protected from light.

Keep out of the reach of children.

HOW SUPPLIED

Doxiva[®] 200 Tablet: Each box contains 100 tablets in Alu-PVDC blister pack.

Doxiva[®] Tablet: Each box contains 50 tablets in Alu-PVDC blister pack.

Doxiva[®] Syrup: Each Amber PET bottle contains 100 ml syrup.