DOXILEY Tablet

(Doxofylline) 400mg

Composition:

Each film coated tablet contains:

Doxofylline.....400mg

(As per innovator's Specs)

What is Doxofylline?

Doxofylline tablet is a medicine that is used for the treatment of asthma, shortness of breath, chronic obstructive pulmonary disease and other conditions.

Doxiley tablet contains doxofylline as an active ingredient.

Doxofylline tablet works by relaxing and opening the airways.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties:

Doxofylline directly relaxes the smooth muscles of the bronchi and pulmonary vessels. In this way, it acts mainly as a bronchodilator, pulmonary vasodilator and as a relaxant of the bronchial muscle. The action of Doxofylline may be mediated, at least in part, by inhibition of the phosphodiesterase leading to an increase in intracellular cyclic AMP which results in smooth-muscle relaxation. At higher concentrations, Doxofylline may inhibit the release of histamine by the cells. Prolonged use of the drug does not lead to addiction.

Pharmacokinetic Properties:

Doxofylline half-life is more than 6 hours, so constant effective plasma levels may be maintained with three administrations a day. The kinetics after a single i.v. and oral administration has been studied in man to define the distribution and absorption of the drug. Plasmatic clearance is high, with values ranging from 444 to 806 ml/min, whereas distribution volume is about 1 l/kg. The mean half-life after intravenous administration was calculated to be 65 minutes (from 40 to 96). After tablet administration, peak plasma levels are reached after 60 minutes, while with the syrup, due to its water and alcohol vehicle, the drug is absorbed more quickly, peak plasma concentration occurring within 30 minutes. Absolute oral bioavailability is about 62.6%; at pH 7.4 the percentage of product bonded



to the plasma proteins is about 48%. Less than 4% of the oral dose is eliminated unchanged in the urine.

Interaction with Other Medicinal Products and Other Forms Of Interaction:

Doxofylline should not be administered with other xanthine preparations. It is recommended to limit consumption of beverages and food containing caffeine. Caution should be exercised in administering Doxiley together with ephedrine or other sympathomimetic drugs. The concurrent administration of many drugs such as erythromycin, TAO, lincomycin, clindamycin, allopurinol, cimetidine, influenza vaccine and propranolol may reduce the hepatic clearance of xanthine derivatives with an increase in the plasmatic levels of the drug. Phenytoin, other anticonvulsants and cigarette smoking may increase the clearance of xanthine derivatives with a reduction of plasmatic half-life. In these cases, it may prove necessary to increase the dosage of the drug.

Pregnancy and Lactation:

Animal tests have shown that the active ingredient of Doxofylline does not interfere with pre- and postnatal growth. However, as there is not sufficient clinical evidence about the effects of the drug during pregnancy, use of the drug during pregnancy should be evaluated carefully case by case on the basis of the risk benefit ratio. The drug is contraindicated during lactation.

Effects on Ability to Drive and Use Machines:

The product does not affect the patient's alertness and therefore does not interfere with his/her ability to drive and use machines.

Overdose:

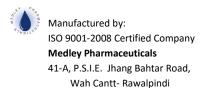
As there is no specific antidote, in case of overdose a symptomatic treatment of cardiovascular collapse should be instituted

Uses:

Doxofylline Tablet is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Asthma
- Shortness Of Breath
- Chronic Obstructive Pulmonary Disease

Side-Effects:





MEDLEY PHARMACEUTICALS

The following is a list of possible side effects that may occur in medicines that contain Troxipide. This is not a comprehensive list. These side effects are possible, but do not always occur. Some of the side effects may be rare but serious. Consult your doctor if you observe any of the following side effects, especially if they do not go away

- Irritability
- Nausea
- Vomiting
- Insomnia
- Arrhythmias
- Seizure

Patients treated with xanthine derivatives may suffer nausea, vomiting, epigastric pain, headache, irritability, insomnia, tachycardia, extrasystoles, tachypnea, and in rare cases, hyperglycemia or albuminuria. In case of overdose severe cardiac arrhythmias and tonic-clonic seizure may occur. These effects may represent the first signs of intoxication. The appearance of side effects may require discontinuation of the treatment which, if necessary, at the physician's discretion, may be resumed at lower doses after all signs and symptoms of toxicity have subsided.

Precautions & How to Use:

Before using this drug, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Pregnant, planning to become pregnant, or breastfeeding
- Xanthine containing products

Presentation:

Pack of 1×10 Tablets in Alu-Alu Blister

