

## Text for leaflet of Fixolin® (Doxofylline INN 400 mg tablet)

### **Description:**

Doxofylline is a type of enzyme inhibitor drugs that is used to treat Asthma and COPD. In animal and human studies, it has shown similar efficacy to theophylline but with significantly less side effects. Doxofylline belongs to category of enzyme inhibitor activity drugs. Specifically, Doxofylline is a new generation long acting oral methylxanthine derivative. Methylxanthines are phosphodiesterase inhibitors. Doxofylline also has antitussive and bronchodilator affects, and acts as a phosphodiesterase inhibitor.

### **Indication:**

Doxofylline is indicated for maintenance therapy in patients suffering with Asthma and Chronic Obstructive Pulmonary Disease (COPD).

### **Dosage and administration:**

**Adults and children > 12 years of age:** 400 mg 1 Tablet twice daily. The dosage may be increased to t.i.d. according to the prescribing physician. The dosage (800 mg/ day) may be decreased according to medical prescription in the

Very elderly patients with concomitant cardiovascular, hepatic, renal and gastric disease, to ½ tablet b.i.d.

**Child (above 3 years of age):** The recommended dosage of Doxofylline is 12 mg / kg daily, divided into 2 doses. In case of unsatisfactory response it can be increased up to 18mg / kg daily under medical supervision.

Doxofylline can be taken with or without food.

### **Side effects:**

After xanthine administration, nausea, vomiting, epigastric pain, cephalalgia, irritability, insomnia, tachycardia, extrasystole, tachypnea 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 1<sup>st</sup> sign of an intoxication. Adverse reactions may cause the withdrawal from treatment; a lower dose rechallenge may start only after the advice of a physician.

### **Contraindications:**

Individuals who have shown hypersensitivity to Doxofylline.  
Patients with acute myocardial infarction and hypotension.

### **Use in lactation:**

Doxofylline is contraindicated in nursing mothers.

**Special precaution:**

The  $t_{1/2}$  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 (CHF), 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. Phenytoin, other anticonvulsants and smoking may cause an increase in clearance with a shorter mean  $t_{1/2}$ .

In these cases, higher doses of doxofylline may be needed.

Use with caution in patients with hypoxemia, hyperthyroidism, liver disease, renal disease, in those with history of peptic ulcer and in elderly. Frequently, patients with CHF have markedly prolonged drug serum levels following discontinuation of doxofylline.

**Use in pregnancy:**

Animal reproduction studies indicate that doxofylline does not cause fatal harm when administered to pregnant animals nor can affect reproduction capacity. However, since there is limited experience in humans during pregnancy, xanthines should be given to a pregnant woman only if clearly needed.

**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.

**COMMERCIAL PRESENTATION**

Box containing 3x10 alu-alu strips. Each tablet contains Doxofylline INN 400 mg.

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**BEXIMCO PHARMACEUTICALS LTD**  
**TONGLI,GAZIPUR**

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