Phylin® (Doxofylline)

400mg Tablets
100mg / 5mL Syrup

فائلن (ڈوکسوفائلن)

۴۰۰ ملی گرام ٹیبلٹس
۱۰۰ ملی گرام/۵ ملی لیٹر سیرپ

QUALITATIVE AND QUANTITATIVE COMPOSITION

Phylin® Tablets 400mg
Each tablet contains:
Doxofylline.....400mg
Innovator's Specification

Phylin® Syrup 100mg/5mL
Each 5mL contains:
Doxofylline…..100mg
Innovator's Specification

DESCRIPTION

Doxofylline is a novel bronchodilator xanthine that differs from theophylline for the presence of a dioxalane group in position 7.

CLINICAL PHARMACOLOGY

Mechanism of action: Doxofylline is a theophylline derivative. Similarly, its mechanism of action is related to the inhibition of phosphodiesterase activities, resulting in bronchodilating activities.

Pharmacodynamics: Like theophylline, doxofylline's mechanism of action is related to the inhibition of phosphodiesterase activities. However, differently from theophylline, doxofylline appears to have decreased affinities toward adenosine A1 and A2 receptors which may account for the better safety profile of the drug.

Pharmacokinetics: The half-life of doxofylline is greater than six hours; so as to allow effective constant plasma levels with a t.i.d. dose regimen. Single dose pharmacokinetic studies in man after oral and intravenous administration defined distribution and absorption of the drug. After oral administration (tablets), peak plasma levels were reached after one hour. Absolute bioavailability is about 62.6%; at pH 7.4 plasma proteins binding the compound is about 48%. Less than 4% of an orally administered dose is excreted unchanged in the urine. Doxofylline is almost completely metabolized in the liver (90% of the total drug clearance). Hydroxyethyltheo phylline is the only detectable circulating metabolite of doxofylline. After repeated administrations doxofylline reaches the steady-state in about 4 days; the elimination half-life during long-term treatment is 8-10 hours: this allows a twice daily dose regimen. No accumulation of the drug was noted after one week of treatment.

INDICATIONS AND USAGE

For the treatment of COPD (Chronic obstructive pulmonary disease), Bronchial asthma and pulmonary disease with spastic bronchial component.

CONTRAINDICATIONS

This product is contraindicated in individuals who have shown hypersensitivity to its components. It is also contraindicated in patients with acute myocardial infarction, hypotension and in lactating women.

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.

USE IN SPECIFIC POPULATION

Use in Pregnancy and Lactation: Animal reproduction studies indicate that Doxofylline does not cause fetal 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. Doxofylline is contraindicated in nursing mothers.

PRECAUTIONS

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, 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. Phenytoins, other anti-convulsants and smoking may cause an increase in clearance with a shorter mean half-life: 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 congestive heart failure have markedly prolonged drug serum levels following discontinuation of the drug.

ADVERSE REACTIONS

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 first sign of intoxication. Adverse reactions may cause the withdrawal from treatment; a lower dose rechallenge may start only after the advice of physician.

DOSAGE AND ADMINISTRATION

Tablets: Elderly Patients: 1/2 tablet two or three times daily.
Adults: 1 tablet two or three times daily or as prescribed by the physician.

Syrup: Elderly Patients: 10mL (2 teaspoonful) two or three times daily.
Children less than 12 years old: 6-9mg/kg twice daily or as directed by the physician.

DOSAGE:

As directed by the physician.

INSTRUCTIONS

Store at 25°C, excursions permitted to 15°C - 30°C.
For Tablets: Protect from sunlight and moisture.
For Syrup: Protect from sunlight.
Keep all medicines out of the reach of children.

PRESENTATION

Phylin® (Doxofylline) tablets 400mg are available in Alu-Alu blister pack of 1 x 10's and 3 x 10's.

Phylin® (Doxofylline) syrup 100mg/5mL are available in 60mL and 120mL PET bottle.

علامات/طریقہ استعمال:

ڈوکسوفائلن مندرجہ ذیل علامات میں تجویز کردہ ہے۔

سی او پی ڈی (کرونِک اَوبسٹرکٹیو پلمونری ڈیزیز)، دمہ اور پھیپھڑوں کے امراض مختلف عمر کے لوگوں میں خوراک ڈاکٹر کی ہدایت کے مطابق تجویز کردہ ہے۔

مضر اثرات:

متلی، اُلٹی، نیند میں کمی، ایلبومینوریا، بے چینی، سر درد، دل کے دھڑکنے کی رفتار میں اضافہ ہو جانا۔

احتیاطی تدابیر:

ڈوکسوفائلن سے حساسیت رکھنے والے مریض احتیاط کریں۔

جگر، گردے اور دل کے مریض احتیاط سے استعمال کریں۔

تمباکو نوشی کرنے والے افراد احتیاط کریں۔

ضرورت پڑھنے کے پیشِ نظر ہی حاملہ خواتین استعمال کریں جبکہ ڈوکسوفائلن کا استعمال دودھ پلانے والی ماؤں میں ممنوع ہے۔

خوراک:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

۲۵ ڈگری سینٹی گریڈ پر رکھیں،

محفوظ رکھنے کی حد ۱۵ سے ۳۰ ڈگری سینٹی گریڈ ہے۔

ٹیبلٹس: سورج کی روشنی اور نمی سے محفوظ رکھیں۔

سیرپ: سورج کی روشنی سے محفوظ رکھیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

For detailed information:

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