

**SCHEDULING STATUS:** S2

**PROPRIETARY NAME:** **SOLPHYLLIN®**

**(AND DOSAGE FORM)** **(SYRUP)**

**COMPOSITION:**

Each 15 ml contains:

Theophylline 80 mg

Etofylline 10 mg

(combined dose equivalent to 110 mg theophylline ethylenediamine)

Methylparaben 0,1 % v/v

Contains sugar: Sucrose 6,994 g

**Excipients:** Apricot Flavour 222459, Amaranth substitute, sucrose, Saccharin sodium, Sodium citrate dihydrate

**PHARMACOLOGICAL CLASSIFICATION:**

A 10.2 Bronchodilators

**PHARMACOLOGICAL ACTION:**

**SOLPHYLLIN** syrup is a stabilised aqueous-alcoholic solution of theophylline with etofylline. Theophylline, a xanthine derivative, has actions resembling those of other xanthine derivatives, caffeine and theobromine. Its diuretic action, although stronger than that of caffeine, is of short duration. It is a more powerful relaxant of involuntary muscle than either theobromine or caffeine. In order to overcome the drawback of theophylline's poor solubility, the theophylline in **SOLPHYLLIN** syrup is incorporated in an aqueous-alcoholic solution and this method has been shown to:

1. be an effective alternative to intravenous therapy and effects could be seen within 10 to 20 minutes
2. induce a comparable clinical response with that obtained from subcutaneous adrenaline.
3. induce a clinical response in acute and chronic bronchial asthma with dyspnoea being controlled within 30 minutes.

Furthermore, gastrointestinal side effects after administration of the aqueous-alcoholic solution of theophylline were minimal. Etofylline, a theophylline derivative in which an alkyl radical is brought into the molecule in position 7, has been found to be less toxic than theophylline, whilst oral administration is not accompanied by gastrointestinal side effects.

**INDICATIONS:**

Acute and chronic bronchial asthma, bronchospasm, bronchitis and emphysema.

N.M

**CONTRAINDICATIONS:**

**SOLPHYLLIN** syrup is contraindicated in diabetes and in alcoholism (rehabilitated alcoholics), and in nursing mothers.

**WARNINGS:**

Children are particularly susceptible to the effects of theophylline and therefore **SOLPHYLLIN** syrup should not be administered more frequently than every eight hours. Overdosage in children can be dangerous, as absorption is unpredictable. It may be characterised by haematemesis, stimulation of the central nervous system and diuresis. **SOLPHYLLIN** syrup should be administered with caution to elderly patients and those suffering from cardiac disease and liver disease. Care should be taken in patients with a history of peptic ulceration.

**DOSAGE AND DIRECTIONS FOR USE:*****Maintenance:***

**Adults:** Three to six medicine measurefuls (15 ml to 30 ml) three times daily after meals.

**Children older than 2 years:** Three medicine measurefuls (15 ml) three times daily after meals.

***Acute attacks:***

**Adults:** Twelve to fifteen medicine measurefuls (60 ml to 75 ml) at onset of attack.

**Children older than 2 years:** Six medicine measurefuls (30 ml) at onset of attack.

The dose should be reduced if central nervous system stimulation is manifested by irritability, restlessness and insomnia.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

The most common side effects encountered with **SOLPHYLLIN** syrup are gastric irritation with nausea and vomiting, gastrointestinal bleeding and central nervous system stimulation. Other side effects are visual disorders, insomnia, headache, anxiety, confusion, restlessness, hyperventilation, vertigo and palpitations. The bronchodilator and toxic effects of theophylline may be enhanced by sympathomimetics and by administration with other xanthines. Smokers may require increased dosage as may patients undergoing routine haemodialysis. Idiosyncrasy may lead to maniacal behaviour, repeated vomiting with extreme thirst, delirium, hyperthermia and convulsions.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

See '**SIDE-EFFECTS AND SPECIAL PRECAUTIONS**'. Emergency treatment may be started immediately. Treatment is symptomatic and supportive.

**IDENTIFICATION:**

**SOLPHYLLIN** syrup is a maroon syrup with an apricot flavour.

**PRESENTATION:**

200 ml Amber glass bottles.

500 ml Amber glass bottles.

200 ml Amber PVC bottles.

200 ml Amber PET bottle

**STORAGE INSTRUCTIONS:**

Store at or below 25 °C. Keep bottle tightly closed and protect from light.

KEEP OUT OF REACH OF CHILDREN.

**REFERENCE NUMBER:**

G 701 (Act 101/1965)

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**

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