SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM:

SOLPHYLLIN® syrup

COMPOSITION:

Each 15 ml contains:

Theophylline	80 mg
Etofylline	10 mg
(combined dose equivalent to 110 mg theophylline ethylenediamine)	
Methylparaben	0,1 % *m/v*
Contains sugar: Sucrose	6,944 g
Contains Sweetener: Saccharin sodium	0,02027 g

Excipients: apricot flavour 222459, amaranth substitute, colour red raspberry F1127, purified water, sodium citrate dihydrate

CATEGORY AND CLASS:

A 10.2 Bronchodilators

PHARMACOLOGICAL ACTION:

SOLPHYLLIN syrup is a stabilised aqueous 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 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 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.

CONTRAINDICATIONS:

SOLPHYLLIN syrup is contraindicated in diabetes and in nursing mothers.

WARNINGS AND SPECIAL PRECAUTIONS:

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. Smokers may require increased dosage as may patients undergoing routine haemodialysis.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrose-isomaltase insufficiency should not take **SOLPHYLLIN.** Sucrose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:

The bronchodilator and toxic effects of theophylline may be enhanced by sympathomimetics and by administration with other xanthines.

HUMAN REPRODUCTION:

Safety in pregnancy and lactation has not been established.

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:

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. Idiosyncracy 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 WARNINGS 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 ºC. Keep bottle tightly closed and protect from light.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G 701 (Act 101/1965)

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

2 May 1988

Botswana: B9300780 S3

Namibia: NS1 14/10.1/0411