

SCHEDULING STATUS:

S2

PROPRIETARY NAME: SOLPHYLLEX SYRUP

DOSAGE FORM: (SYRUP)

COMPOSITION:

Each 30 ml contains:

Theophylline 100 mg

Etofylline 10 mg

Diphenylpyraline hydrochloride 8 mg

Ammonium chloride 720 mg

Sodium citrate 300 mg

Alcohol 0,36 % v/v

Contains sugar:

Sucrose 26,2 g

Contains sweetener:

Saccharine sodium 0,0322 g

List of excipients: blackcurrant flavour, cherry Essence No.1, caramel powder, glycerol, menthol and xanthan gum,

CATEGORY AND CLASS

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION:

SOLPHYLLEX SYRUP is an expectorant cough syrup, which, in addition to the expectorants, contains the bronchodilators, theophylline and etofylline and the antihistamine, diphenylpyraline hydrochloride.

SOLPHYLLEX SYRUP contains alcohol, which has been added to aid the absorption of theophylline and etofylline. Ammonium chloride and sodium citrate exert an expectorant action which aids the expulsion of thick bronchial mucous. The bronchial dilating action of theophylline and etofylline reduces spasm of the bronchial tubes thereby making breathing easier. Diphenylpyraline hydrochloride, an effective antihistamine, has been incorporated to cater for coughs associated with allergic manifestation.

INDICATIONS:

SOLPHYLLEX SYRUP is indicated for the prompt relief of coughs associated with respiratory infection, asthma and allergy. Being non-narcotic and non-addictive, **SOLPHYLLEX SYRUP** can be used for prolonged therapy.

CONTRAINDICATIONS:

SOLPHYLLEX SYRUP is contraindicated in diabetes, alcoholism (rehabilitated alcoholics), severe hypotension, peptic ulcer, gout, renal or hepatic disease and hypersensitivity to antihistamines.

WARNINGS AND SPECIAL PRECAUTIONS:

This medicine may lead to drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants.

When given orally in excessive dosage all the constituents may cause gastrointestinal disturbances. However, when the recommended dosage is used, these symptoms are usually infrequent and mild.

INTERACTIONS:

The bronchodilator and toxic effects of theophylline may be enhanced by sympathomimetics and by administration with other xanthines. Smokers may require increased doses as may patients undergoing routine haemodialysis.

Diphenylpyraline hydrochloride has anticholinergic properties and should be used with care in conditions such as glaucoma and prostatic hypertrophy. The effects of atropine and tricyclic antidepressants may be enhanced.

HUMAN REPRODUCTION:

Safety and/or efficacy has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Do not exceed the recommended dose

Adults: Three medicine measuresful (15 ml) three times daily after meals and at bedtime.

Children 2 to 12 years: Two medicine measuresful (10 ml) three times daily after meals and at bedtime.

SIDE EFFECTS

Gastrointestinal disturbances.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Large doses of theophylline will cause gastric irritation. Large doses of ammonium chloride will cause similar symptoms including nausea, vomiting, thirst, also headache, hyperventilation, progressive drowsiness, mental confusion and hyperchloraemic acidosis. Acidosis and electrolyte loss may be corrected by intravenous administration of sodium bicarbonate and potassium gluconate. Large doses of antihistamines will cause sedation varying from slight drowsiness to deep sleep, also dizziness, muscular weakness and inco-ordination. In infants and children the antihistamines often act as cerebral stimulants and may cause hyperpyrexia and convulsions. No fatal effects have ever been reported with the usual therapeutic doses, but rare fatalities have occurred in young children who had ingested large overdoses. Since there is no specific antidote for acute antihistamine poisoning (histamine must not be used) it is important to keep **SOLPHYLLEX SYRUP** out of the reach of young children. If a large overdose has just been taken, empty the stomach by gastric lavage.

IDENTIFICATION:

SOLPHYLLEX SYRUP is a clear, brown syrup with a cherry and blackcurrant flavour.

PRESENTATION:

Glass bottles of 100 ml and 200 ml.

200 ml medical round amber PET bottles with child proof screw-on closure.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Keep the bottle tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G703 (Act101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69, Bryanston 2021

www.adcock.com

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