PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

SOLPHYLLEX SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 30 mL contains:

Theophylline (anhydrous)	100 mg
Etofylline (Hydroxyethyltheophylline)	10 mg
Diphenylpyraline hydrochloride	8 mg
Ammonium chloride	720 mg
Sodium citrate dihydrate	300 mg
Alcohol	0,5 % v/v
Contains sugar:	
Sucrose	17,13 g
Contains sweetener:	
Saccharin sodium	32,20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Posology and method of administration

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.

Do not exceed the recommended dose (see section 4.9).

Renal impairment:

Patients undergoing routine haemodialysis may require increased doses.

Method of administration

Oral administration only.

Shake well before use.

4.3 Contraindications

Hypersensitivity to theophylline, hydroxyethyltheophylline, diphenylpyraline, ammonium chloride, sodium citrate or any of the excipients listed in section 6.1.

SOLPHYLLEX SYRUP is contraindicated in patients suffering from:

- diabetes
- hypersensitivity to antihistamines
- renal or hepatic disease
- severe hypotension
- peptic ulcer
- gout
- alcoholism (rehabilitated alcoholics).

4.4 Special warnings and precautions for use

- 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.
- SOLPHYLLEX SYRUP contains 17,13 g of sucrose per 30 mL of syrup which may have an effect on the effects of the glycaemic control of patients with diabetes mellitus.
- SOLPHYLLEX SYRUP contains 0,15 mL of alcohol (ethanol) in each 30 mL of syrup, expressed as 0.5% (v/v). The alcohol in this medicine may alter the effects of other medicines.
- This medicinal product contains 73,6 mg sodium per 30 mL or 2,45 mg/mL of syrup, equivalent to 5,5 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interactions with other medicinal products and other forms of interaction

- The bronchodilator and toxic effects of theophylline may be enhanced by *sympathomimetics* and by administration with other *xanthines*.
- Smokers may require increased doses.
- 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.

- This medicine may lead to drowsiness and impaired concentration that may be aggravated by simultaneous intake of *alcohol* or other *central nervous system depressants* (see section 4.3 and 4.7).

4.6 Fertility, pregnancy, and lactation

Safety and/or efficacy in fertility, pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

SOLPHYLLEX SYRUP may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should not drive, use machinery, or perform any tasks that require concentration, until they are certain that SOLPHYLLEX SYRUP does not adversely affect their ability to do so (see section 4.8).

4.8 Undesirable effects

Gastrointestinal disturbances.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit /risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Adverse Drug Reactions may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com.

4.9 Overdose

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 in co-ordination.

Paediatric Population

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, contact the nearest doctor, hospital or poison control center.

5. PHARMACOLOGICAL PROPERTIES

A 10.1 Antitussives and expectorants.

ATC: R07AB.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Caramel Powder E150 EF
- Flavour Blackcurrant NE 53984
- Flavour Cherry No. 1 BBA
- Glycerol (E 422)
- L-Menthol
- Rectified Extra Neutral Alcohol (96 %)
- Saccharin Sodium 500
- Sucrose solution (65° Brix)
- Purified Water
- Xanthum gum

6.2 Incompatibilities

No information available.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep the bottle tightly closed.

6.5 Nature and contents of container

Glass bottles of 100 mL and 200 mL.

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

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

G703 (Act101/1965).

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

16 August 1976.

10. DATE OF REVISION OF THE TEXT

21 January 2025.