PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ACTOPHLEM COUGH 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.

ACTOPHLEM COUGH SYRUP is a clear brown syrup with a blackcurrant flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

ACTOPHLEM COUGH SYRUP is indicated for the alleviation of cough.

4.2 Posology and method of administration

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

Children (7 years and older): Two medicine measures (10 mL) three times daily after meals.

Children (3 to 6 years): One medicine measure (5 mL) three times daily after meals.

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

Children:

Children are particularly sensitive to the effects of theophylline and it should not be administered more frequently than every eight hours.

Elderly or Cardiac patients:

Theophylline should be administered with caution to elderly patients and those suffering from cardiac disease.

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

ACTOPHLEM COUGH SYRUP is contraindicated in patients suffering from:

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

4.4 Special warnings and precautions for use

- Diphenylpyraline hydrochloride may precipitate fits in epileptics.
- ACTOPHLEM COUGH 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.
- ACTOPHLEM COUGH 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).
- The concomitant administration of other *theophylline containing preparations* and ACTOPHLEM COUGH SYRUP may lead to toxic levels of theophylline and patients should be cautioned accordingly.
- The warning symptoms of damage caused by *ototoxic drugs* may be masked and the metabolism of drugs in the liver may be affected.
- Diphenylpyraline hydrochloride may enhance the sedative effect of the central nervous system depressants including *alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillizers.*

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

ACTOPHLEM COUGH 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 be warned against taking charge of vehicles or machinery or

performing potentially hazardous tasks where loss of concentration may lead to accidents.

4.8 Undesirable effects

Tabulated summaries

System organ Class	Frequent	Undesirable effect
Blood and lymphatic system disorders	Unknown	Blood dyscrasias including agranulocytosis and haemolytic anaemia may occur.
Immune system disorders	Unknown	Allergy and anaphylaxis may occur.
Metabolism and nutrition disorders	Unknown	Anorexia.
Psychiatric disorders	Unknown	Anxiety, elation or depression, irritability, nightmares.
Nervous system disorders	Unknown	Insomnia, headache, confusion, restlessness, vertigo, nervousness, tremors.
	Frequent	Sedation which can vary from slight drowsiness to deep sleep, and includes the inability to concentrate, lassitude, dizziness, incoordination, convulsions, dryness of the mouth, tingling, heaviness and weakness of the hands may occur.
Eye disorders	Unknown	Visual disorders.
Ear and labyrinth disorders	Unknown	Tinnitus.

Cardiac disorders	Unknown	Palpitations, tachycardia.
Vascular disorders	Frequent	Hypotension.
Respiratory, thoracic, and mediastinal disorders	Unknown	Hyperventilation, tightness of the chest.
Gastrointestinal disorders	Frequent	Nausea, vomiting, gastrointestinal bleeding, diarrhoea or constipation, epigastric pain.
Musculoskeletal and connective tissue disorders	Unknown	Muscle twitching,
	Frequent	Muscular weakness.
Renal and urinary disorders	Unknown	Difficulty in micturition.

Paediatric population

In infants and children diphenylpyraline hydrochloride may act as a cerebral stimulant.

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

Ammonium chloride causes symptoms such as nausea, vomiting, thirst, headache, hyperventilation, progressive drowsiness, hypokalaemia, mental confusion and

hyperchloraemic acidosis.

Overdosage of theophylline may lead to maniacal behaviour, repeated vomiting with extreme thirst, delirium, hyperthermia and convulsions.

Paediatric Population

It is important to keep ACTOPHLEM COUGH SYRUP out of reach of young children.
If a large overdose has just been taken, contact the nearest doctor, hospital or poison control center.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

A 10.1 Antitussives and expectorants.

ATC: R07AB.

5.1 Pharmacodynamic properties

ACTOPHLEM COUGH SYRUP has bronchodilatory, antihistaminic and expectorant properties.

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

• Glycerol (E 422)

• L-Menthol

• Rectified Extra Neutral Alcohol (96,0 %)

• 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

100 mL, 200 mL and 500 mL amber glass bottles with white polypropylene caps and expanded polyethylene liners.

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

W/10.1/194.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

4 November 1988.

10. DATE OF REVISION OF THE TEXT

16 January 2025.