PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ACTOPHLEM COUGH SYRUP

Each 30 ml contains:

Theophylline	**100 mg**
Etofylline (hydroxyethyltheophylline)	**10 mg**
Diphenylpyraline hydrochloride	**8 mg**
Ammonium chloride	**720 mg**
Sodium citrate dihydrate	**300 mg**

Contains sugar: 17,13 g sucrose

Contains sweetener: 32,20 mg saccharin sodium

Contains alcohol: 0.5% (v/v)

Read all of this leaflet carefully because it contains important information for you.

ACTOPHLEM COUGH SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ACTOPHLEM COUGH SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACTOPHLEM COUGH SYRUP with any other person.

- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What ACTOPHLEM COUGH SYRUP is and what it is used for.
2. What you need to know before you take ACTOPHLEM COUGH SYRUP.
3. How to take ACTOPHLEM COUGH SYRUP.
4. Possible side effects.
5. How to store ACTOPHLEM COUGH SYRUP.
6. Contents of the pack and other information.

1. What ACTOPHLEM COUGH SYRUP is and what it is used for

ACTOPHLEM COUGH SYRUP belongs to a group of medicines used in the treatment of cough and cold ailments.

ACTOPHLEM COUGH SYRUP is intended for the alleviation of cough.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACTOPHLEM COUGH SYRUP

Do not take ACTOPHLEM COUGH SYRUP if you suffer from:

- Hypersensitivity (you are allergic) to theophylline, etofylline, diphenylpyraline hydrochloride, ammonium chloride, sodium citrate or any of the other ingredients of ACTOPHLEM COUGH SYRUP (listed in section 6)
- kidney or liver disease
- diabetes
- severe hypotension (low blood pressure)

- peptic ulcers (a painful sore that develops on the lining of your stomach, small intestine, or oesophagus)
- gout (a condition that causes sudden and severe pain, redness, and swelling in your joints.)
- alcoholism (including rehabilitated alcoholics).

Warnings and precautions

Special care should be taken:

- If you suffer from epilepsy (fits/seizures). ACTOPHLEM COUGH SYRUP contains diphenylephrine hydrochloride, which may trigger seizures/fits.
- When administering ACTOPHLEM COUGH SYRUP, which contains theophylline, to elderly patients, and to patients with heart problems, as this may worsen the patient's condition (see section 3. 'How to take ACTOPHLEM COUGH SYRUP)
- if you are undergoing routine haemodialysis treatment (for certain kidney problems), as you may require increased doses of ACTOPHLEM COUGH SYRUP (see section 3. 'How to take ACTOPHLEM COUGH SYRUP).

Other medicines and ACTOPHLEM COUGH SYRUP

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

The below medicines/medicine groups may interact with and alter the effectiveness of ACTOPHLEM COUGH SYRUP:

- Taking xanthine or sympathomimetics (i.e. medicines that mimic the effects of adrenaline by stimulating the nervous system like caffeine and asthma medication) with theophylline can make theophylline work

too strongly, which might lead to more intense effects and increase the risk of side effects. Theophylline, an ingredient in ACTOPHLEM COUGH SYRUP, is used to help open up your airways, but combining it with these other drugs can make it more likely to cause problems.

- if you are a smoker, you should speak to your healthcare provider as you might need higher amounts of medication to get the same effect as non-smokers.
- diphenylpyraline hydrochloride, as contained in ACTOPHLEM COUGH SYRUP can affect your body's natural chemicals and might not be safe for people with certain conditions like glaucoma (eye pressure issues) or prostate problems. It could also make the effects of medications like atropine (often used for various conditions) and tricyclic antidepressants (a type of mood medication) stronger.
- this medicine might make you feel sleepy and affect your ability to focus. Taking it with other medications that also make you sleepy can make these effects worse.
- if you take ACTOPHLEM COUGH SYRUP along with other medicines that also contain theophylline, it can lead to too much theophylline in your system, which could be harmful, therefore use with caution or speak to your doctor if you are not sure.
- taking ACTOPHLEM COUGH SYRUP with certain medicines might hide warning signs of hearing problems and can also change how your liver processes other medicines. This means it could be harder to notice if your hearing is being affected or if other medications are working differently.
- diphenylpyraline hydrochloride, as contained in ACTOPHLEM COUGH SYRUP, can make you feel even more sleepy or relaxed if you’re also taking other medicines that depress the central nervous system, like alcohol, strong painkillers, or sedatives.

ACTOPHLEM COUGH SYRUP with alcohol

ACTOPHLEM COUGH SYRUP contains 0,15 mL of alcohol (ethanol) in each 30 mL dose which is equivalent to 0,005 mL of alcohol (ethanol) per mL of syrup.

ACTOPHLEM COUGH SYRUP, can further impair your concentration and make you feel even more sleepy or relaxed if also taken with alcohol.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery

ACTOPHLEM COUGH SYRUP may cause drowsiness, impaired concentration and visual disturbances which may affect your ability to perform skilled tasks; if you are affected, you should not drive or operate machinery.

It is not always possible to predict to what extent ACTOPHLEM COUGH SYRUP may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ACTOPHLEM COUGH SYRUP affects you (see section 4).

ACTOPHLEM COUGH SYRUP contains:

Sucrose (a form of sugar)

If you suffer from diabetes mellitus. ACTOPHLEM COUGH SYRUP contains 17,13 g of sucrose per 30 mL or 0,5 mg/mL of syrup. This should be taken into account if you suffer with diabetes mellitus. If you have been told by your doctor

that you have an intolerance to some sugars. You should contact your doctor before taking this medicinal product. This medicine may also be harmful to the teeth.

Sodium (a component of table salt)

This medicine contains 2,45 mg sodium (main component of cooking/table salt) in each mL of syrup. This is equivalent to 5,5 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE ACTOPHLEM COUGH SYRUP

Do not share medicines prescribed for you with any other person.

Always take ACTOPHLEM COUGH SYRUP medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

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.

For children

If you are giving this medicine to a child, be careful not to administer it more frequently than every eight hours as children are particularly susceptible to the effects of theophylline, an ingredient in ACTOPHLEM COUGH SYRUP.

In elderly or cardiac patients

You should use ACTOPHLEM COUGH SYRUP with caution if you're older or have heart problems as you may be more susceptible to the effects of theophylline, an ingredient in ACTOPHLEM COUGH SYRUP.

In patients with kidney problems

If you're on regular kidney dialysis, you might need higher doses of ACTOPHLEM COUGH SYRUP. Speak to your doctor before taking this medicine.

ACTOPHLEM COUGH SYRUP is to be taken orally.

Shake well before use.

If you take more ACTOPHLEM COUGH SYRUP than you should

Taking more than the recommended dose of ACTOPHLEM COUGH SYRUP, may lead to nausea, vomiting, thirst, headache, hyperventilation (rapid breathing), increasing drowsiness, low blood-potassium levels (which may present as weakness, muscle cramps, rapid beating of the heart), mental confusion and electrolyte imbalances in the blood which can lead to kidney failure due to ammonium chloride, an ingredient of ACTOPHLEM COUGH SYRUP.

It may also lead to maniacal behaviour, repeated vomiting with extreme thirst, delirium, hyperthermia (abnormally high body temperature) and convulsions (seizures/fits) due to theophylline, an ingredient of ACTOPHLEM COUGH SYRUP.

It is important to keep ACTOPHLEM COUGH SYRUP COUGH SYRUP out of reach and sight of young children.

Treatment is symptomatic and supportive.

In the event of overdosage, consult your doctor or pharmacist even if you do not notice the symptoms. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ACTOPHLEM COUGH SYRUP

Do not administer a double dose to make up for forgotten individual doses.

4. **POSSIBLE SIDE EFFECTS**

ACTOPHLEM COUGH SYRUP can have side effects.

Not all side effects reported for ACTOPHLEM COUGH SYRUP are included in this leaflet. Should your general health worsen or if you experience any

untoward effects while taking, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking ACTOPHLEM COUGH SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ACTOPHLEM COUGH SYRUP. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Tightness of the chest
- tachycardia
- palpitations.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common side effects:

- Nausea
- vomiting
- gastrointestinal bleeding/ pain in the gastric area
- diarrhoea
- constipation
- sedation which can vary from slight drowsiness to deep sleep, and includes the inability to concentrate

- lassitude/dizziness
- incoordination
- convulsions (fits)
- dryness of the mouth
- tingling and heaviness and weakness of the hands
- hypotension.

Uncommon side effects:

- Blood disorders including anaemia
- hyperventilation
- anorexia
- anxiety/irritability/restlessness
- elation or depression
- nightmares
- insomnia
- headache
- confusion
- vertigo
- visual disorders
- nervousness
- hyperventilation
- tinnitus
- hypotension (low blood pressure)
- dryness of the mouth
- twitching/tremors
- muscular weakness
- difficulty in urinating.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Paediatric population

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

Reporting of side effects

If you get side effects talk to your doctor or pharmacist or nurse.

You can also report side effects to SAHPRA via the '**Med Safety App**' (Med Safety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of **ACTOPHLEM COUGH SYRUP.**

You may also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com.

5. HOW TO STORE ACTOPHLEM COUGH SYRUP

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the bottle tightly closed.

Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g.

toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ACTOPHLEM COUGH SYRUP contains:

The active substances are:

- theophylline 100 mg
- etofylline 10 mg
- diphenylpyraline hydrochloride 8 mg
- ammonium chloride 720 mg
- sodium citrate dihydrate 300 mg.

The other ingredients are:

- blackcurrant flavour NE53984
- caramel powder E150 EF
- glycerol (E 422)
- l-menthol
- saccharin sodium
- sucrose solution (65° brix)
- xanthan gum
- purified water
- rectified extra neutral alcohol (96,0%).

What ACTOPHLEM COUGH SYRUP looks like and contents of the pack:

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

It is packed in 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.

Holder of Certificate of Registration

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Access to the corresponding professional information