PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

SOLPHYLLEX 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.

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

- Keep this leaflet. You may need to read it again.

- Do not share SOLPHYLLEX 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 SOLPHYLLEX SYRUP is and what it is used for.
2. What you need to know before you take SOLPHYLLEX SYRUP.
3. How to take SOLPHYLLEX SYRUP.
4. Possible side effects.
5. How to store SOLPHYLLEX SYRUP.
6. Contents of the pack and other information.

1. What SOLPHYLLEX SYRUP is and what it is used for

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

SOLPHYLLEX SYRUP is indicated for the prompt relief of coughs associated with respiratory infection, asthma and allergy. SOLPHYLLEX SYRUP can be used for prolonged therapy as it is considered a non-addictive.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLPHYLLEX SYRUP

Do not take SOLPHYLLEX 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 SOLPHYLLEX SYRUP (listed in section 6)
- diabetes (high blood sugar)

- hypersensitivity to antihistamines (medications used to relieve allergy symptoms)
- kidney or liver disease
- 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 take more than the recommended dose as you may experience gastrointestinal (stomach) discomfort like nausea, vomiting and pain.
- if you are undergoing routine haemodialysis treatment (for certain kidney problems), as you may require increased doses of SOLPHYLLEX SYRUP (see section 3. ‘How to take SOLPHYLLEX SYRUP).

Other medicines and SOLPHYLLEX 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 SOLPHYLLEX 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 SOLPHYLLEX 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 SOLPHYLLEX 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.
- SOLPHYLLEX 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.

SOLPHYLLEX SYRUP with alcohol

- SOLPHYLLEX 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.
- SOLPHYLLEX 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

SOLPHYLLEX SYRUP may cause drowsiness and impaired concentration 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 SOLPHYLLEX 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 SOLPHYLLEX SYRUP affects you (see section 4).

SOLPHYLLEX SYRUP contains

Sucrose (a form of sugar)

If you suffer from diabetes mellitus. SOLPHYLLEX 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 SOLPHYLLEX SYRUP

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

Always take SOLPHYLLEX 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 (2-12 years): Two medicine measures (10 mL) three times daily after meals and at bedtime.

You should not exceed the recommended dose (see *Warnings and precautions*).

SOLPHYLLEX SYRUP is to be taken orally.

In patients with kidney problems

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

If you take more SOLPHYLLEX SYRUP than you should

Taking more than the recommended dose of SOLPHYLLEX SYRUP, will cause stomach irritation due to theophylline, an ingredient of SOLPHYLLEX SYRUP.

It may also 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 SOLPHYLLEX SYRUP.

Feeling sleepy, dizziness, muscular weakness and poor coordination may also occur when too much SOLPHYLLEX SYRUP is taken.

In infants and children, large doses may lead to seizures and fevers due to antihistamines, a constituent of SOLPHYLLEX SYRUP.

Since there is no specific antidote for antihistamine (a component of SOLPHYLLEX SYRUP) poisoning, it is important to keep SOLPHYLLEX SYRUP out of the reach and sight of young children.

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 SOLPHYLLEX SYRUP

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

4. POSSIBLE SIDE EFFECTS

SOLPHYLLEX SYRUP can have side effects.

Not all side effects reported for SOLPHYLLEX 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 SOLPHYLLEX 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 SOLPHYLLEX SYRUP. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Gastrointestinal disturbances (nausea, vomiting, pain in the stomach)

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

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 **SOLPHYLLEX SYRUP.**

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

Adcock.AEReports@adcock.com.

5. HOW TO STORE SOLPHYLLEX SYRUP

Store all medicines out of reach and sight 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 SOLPHYLLEX 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 SOLPHYLLEX SYRUP looks like and contents of the pack

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

It is packed in glass bottles of 100 mL and 200 mL.

The 200 mL medical round amber PET bottles have a child proof screw-on closure.

Holder of Certificate of Registration

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Access to the corresponding professional information