

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

ALCOPHYLLEX Mixture (Oral liquid)

Theophylline 16,667 mg, hydroxyethyl theophylline (etofylline) 1,667 mg,
diphenhydramine hydrochloride 6,667 mg, ammonium chloride 120 mg, sodium citrate
50 mg

Preservatives: Methylparaben 0,1 % m/v and propylparaben 0,015 % m/v

Alcohol 0,5 % v/v

Contains sugar: Sucrose 3,266 g

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ALCOPHYLLEX with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

What is in this leaflet

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

1. What ALCOPHYLLEX is and what it is used for

ALCOPHYLLEX is used to relieve a tight chest caused by asthma, colds, bronchitis etc.

2. What you need to know before you take ALCOPHYLLEX

Do not take ALCOPHYLLEX:

- If you are hypersensitive (allergic) to theophylline, hydroxyethyl theophylline (etofylline), diphenhydramine hydrochloride, ammonium chloride, sodium citrate or any of the other ingredients of ALCOPHYLLEX.
- If your baby was born alive before 37 weeks of pregnancy has been completed.
- If you have porphyria (a group of rare disorders of certain enzymes).
- If you have a serious lung disease (for example, asthma attacks).
- If you suffer from liver or kidney problems.
- If you have a buildup of acid in the body due to kidney disease or kidney failure or when the lungs cannot remove all of the carbon dioxide the body produces.
- If you suffer from an electrolyte imbalance e.g., hypocalcaemia (low level of calcium

in the blood).

- If you have hypochlorhydria (production of gastric acid in the stomach is absent or low).
- If you suffer from epilepsy (fits) or have had them in the past.
- Do not give ALCOPHYLLEX to babies or children under the age of 2 years.
- If you are taking monoamine oxidase inhibitors (MAOIs) (anti-depressants) with ALCOPHYLLEX
- Recent heart attack/ acute onset of a heart rate that exceeds the normal resting rate
- Using ALCOPHYLLEX with certain antihistamines i.e. ephedrine.

Warnings and precautions

Take special care with ALCOPHYLLEX:

- If you have a persistent cough, persisting for more than a week, please consult a doctor
- If you have a stomach ulcer.
- If you have an overactive thyroid gland.
- If you have high blood pressure, irregular heartbeat, or any heart disease.
- If you are elderly.
- If you suffer from alcoholism.
- If you have glaucoma (a condition of the eye which leads to blindness), urinary retention (inability to urinate), or prostatic hypertrophy (enlargement of the prostate gland).
- If you have a type of illness characterized by a sudden onset of fever, which is an increase in internal body temperature to levels above normal (acute febrile illness).
- If you have low levels of oxygen in your body tissues (severe hypoxia).

- If you have a condition that causes the right side of the heart to fail (cor pulmonale).
- If you have a condition caused by too much fluid in the lungs (acute pulmonary oedema).
- If you have chronic lung disease, liver, and kidney problems.
- If you use high doses of diphenhydramine-containing medicines, such as ALCOPHYLLEX, it may lead to serious heart problems, seizures, coma and death.
- The elderly patients, are particularly prone to dizziness, sedation, confusion, hypotension (low blood pressure) and anticholinergic effects (dry mouth, blurry vision, dry eyes, constipation, or urinary problems)
- May cause excitability especially in children.
- ALCOPHYLLEX is unsuitable for children suffering from diabetes mellitus.

Other medicines and ALCOPHYLLEX

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

- The use of ALCOPHYLLEX with other *xanthines* (e.g., aminophylline) should be avoided.
- The following medicines may cause ALCOPHYLLEX to stay in the body for longer and thereby increases the possibility of side effects; *allopurinol* (to treat gout), *cimetidine* (used to relieve the symptoms of heartburn), *propranolol*, *verapamil*, (used to treat heart problems), *erythromycin*, *tetracycline*, *quinolones* (antibiotics), *isoniazid* (used in the treatment of TB), *disulfiram* (to treat alcoholism), *fluvoxamine* (used to treat depression), *interferon alfa* (used in the treatment of some cancers), *oral contraceptives* (birth control pill), *caffeine*, *thiabendazole* (used to treat worms), *BCG vaccination* and *influenza vaccination*.

- The following medicines may decrease the effectiveness of ALCOPHYLLEX;
phenytoin and other convulsants (used to treat epilepsy), *ritonavir* (used in the treatment of HIV), *rifampicin* (used in the treatment of TB), *sulfinpyrazone* (used to treat gout) and *cigarette smoking*.
- ALCOPHYLLEX can cause hypokalaemia (concentration of potassium in the blood is low) if used with *beta₂-agonists* (used in the treatment of asthma), *corticosteroids* (used to treat various conditions including arthritis, rheumatism, allergic conditions, and certain skin diseases), and *diuretics* (water tablets).
- ALCOPHYLLEX may increase the side effects of *lithium* (used in the treatment of depression), *halothane*, *ketamine* and *adenosine* when taken together.
- There is a possibility of ALCOPHYLLEX causing side effects increase when used together with *monoamine oxidase inhibitors* (used in the treatment of depression).
- The effect of ALCOPHYLLEX to make you feel drowsy may be increased if it is taken at the same time as *hypnotics* (e.g., flunitrazepam), *alcohol*, *barbiturates* (e.g., phenobarbital), and *sedatives* (e.g., zolpidem).
- ALCOPHYLLEX may mask the warning signs of damage caused by *aminoglycoside antibiotics* (e.g., gentamicin).
- ALCOPHYLLEX may interfere with the results of skin tests and should be stopped several days before the tests.
- ALCOPHYLLEX can enhance the absorption of aluminium from the gastrointestinal tract.
- Xanthine containing beverages (e, g: tea, coffee, cocoa) may interfere with some laboratory tests for theophylline.

Taking ALCOPHYLLEX with food and drink:

ALCOPHYLLEX should be taken with food to minimise possible side effects.

Pregnancy, breastfeeding and fertility

Safety for use during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking ALCOPHYLLEX.

Driving and using machines

ALCOPHYLLEX can lead to drowsiness and impaired concentration. You should therefore not drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

ALCOPHYLLEX contains sucrose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ALCOPHYLLEX.

ALCOPHYLLEX contains alcohol:

This medicine contains 0,021 mg of alcohol (ethanol) in each 5 mL which is equivalent to 0,5 % v/v. The small amount of alcohol in this medicine will not have any noticeable effects.

ALCOPHYLLEX contains sodium:

This medicine contains 50 mg sodium (main component of cooking/table salt) in each 5 mL or 10 mg/mL of syrup. This is equivalent to 0,5 % of the recommended maximum

daily dietary intake of sodium for an adult.

3. How to take ALCOPHYLLEX

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

Do not exceed the recommended dose. Always take ALCOPHYLLEX exactly as described in this leaflet or as your doctor, or pharmacist or nurse have told you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that ALCOPHYLLEX is too weak or too strong, talk to your doctor or pharmacist. If ALCOPHYLLEX does not seem to be working as well as usual, talk to your doctor as soon as possible. Your chest problem may be getting worse, and you may need other, or additional medicines. Do not take extra or higher doses of ALCOPHYLLEX unless your doctor tells you to.

The usual dose for *adults*: 2 to 3 medicine measures (10 to 15 mL) every four hours.

The usual dose for *children 2 to 6 years*: ½ to 1 medicine measure (2,5 to 5 mL) every four hours.

The usual dose for *children 7 to 12 years*: 1 to 2 medicine measures (5 to 10 mL) every four hours.

Oral administration only.

Shake the bottle before use.

Doses must be taken orally with an adequate amount of fluid (half to one glass)

If you take more ALCOPHYLLEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. You may experience nausea, vomiting, diarrhoea, rapid breathing, shortness of breath, muscle weakness, shivering, restlessness, high or low blood pressure, drowsiness, irregular heartbeat, coma, and convulsion.

If you forget to take ALCOPHYLLEX

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

4. Possible Side Effects

ALCOPHYLLEX can have side effects.

Not all side effects reported for ALCOPHYLLEX are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ALCOPHYLLEX, please consult your healthcare professional for advice.

If any of the following happens, stop using ALCOPHYLLEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, 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

allergic reaction to ALCOPHYLLEX. 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:

- tight chest,
- changes in the way your heart beats,
- difficulty urinating or less urine than is normal for you,
- blurred vision,
- muscle weakness,
- incoordination,
- convulsions.

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

Tell your doctor if you notice any of the following:

- difficulty falling asleep,
- ringing in the ears,
- feeling anxious,
- restlessness or nervousness,
- headache,
- dizziness,
- change in appetite,
- excessive bruising or bleeding (when you cut your skin),
- nausea and vomiting,

- stomach pains,
- diarrhoea,
- constipation,
- dryness of the mouth,
- fatigue,
- slight drowsiness or deep sleep.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ALCOPHYLLEX.

5. How to store ALCOPHYLLEX

STORE ALL MEDICATION OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store in the original container. Keep the container tightly closed. Protect from light.

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 ALCOPHYLLEX contains:

Each 5 mL contains:	
Theophylline	16,667 mg
Hydroxyethyl Theophylline (etofylline)	1,667 mg
Diphenhydramine Hydrochloride	6,667 mg
Ammonium Chloride	120 mg
Sodium Citrate	50mg

The preservatives methylparaben 0,1 % m/v, propylparaben 0,015 % m/v and alcohol 0,5 % v/v.

Other inactive ingredients are ethanol, Caramel colorant [E150], citric acid monohydrate [E330], methylparaben [E218], propylparaben [E216], purified water, Raspberry flavour, sucrose.

What ALCOPHYLLEX looks like and contents of the pack

A dark brown liquid with an odour of raspberry.

100 mL & 200 mL:

Amber PVC bottle with LLDPE pilfer proof closure.

Amber glass bottle with white polypropylene closure cap.

Amber PET medical round bottle with white polypropylene and HDPE child-proof screw-on cap.

2.5 L:

Amber HDPE container with white polypropylene screw on closure with EXPE liner.

Not all pack sizes may be marketed at the same time.

Holder of Certificate of Registration

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