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 you 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 *beta$_2$-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 antibacterials* (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

Adcock Ingram Limited

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1685

Customer Care: 0860 ADCOCK / 232625.

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PASIËNT INLIGTINGSBLAD

SKEDULERINGSTATUS:

S2

ALCOPHYLLEX Mixture (Orale vloeistof)

Teofillien 16,667 mg, hidroksiëtielteofillien (etofillien) 1,667 mg,

difenhidramienhidrochloried 6,667 mg, ammoniumchloried 120 mg, natriumsitraat 50 mg

Preserveermiddels: Metielparabeen 0,1 % *m/v* en propielparabeen 0,015 % *m/v*

Alkohol 0,5 % *v/v*

Bevat suiker: Sukrose 3,266 g

Lees hierdie hele biljet noukeurig deur, want dit bevat belangrike inligting vir u.

ALCOPHYLLEX is beskikbaar sonder 'n doktersvoorskrif, vir u om 'n minder ernstige siekte te behandel. Nietemin moet u steeds ALCOPHYLLEX versigtig gebruik om die beste resultate te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie ALCOPHYLLEX met enige ander persoon deel nie.
- Vra u apteker of u meer inligting of advies benodig.
- U moet 'n dokter spreek indien u simptome vererger of nie na 5 dae verbeter nie .

Wat is in hierdie biljet

1. Wat ALCOPHYLLEX is en waarvoor dit gebruik word
2. Wat u moet weet voordat u ALCOPHYLLEX neem
3. Hoe om ALCOPHYLLEX te neem
4. Moontlike newe-effekte
5. Hoe om ALCOPHYLLEX te bêre
6. Inhoud van die verpakking en ander inligting.

1. Wat ALCOPHYLLEX is en waarvoor dit gebruik word

ALCOPHYLLEX word gebruik om 'n benoude bors te verlig wat veroorsaak word deur asma, verkoue, bronchitis, ens.

2. Wat u moet weet voordat u ALCOPHYLLEX neem

Moenie ALCOPHYLLEX neem nie:

- Indien u hipersensitief (allergies) is vir teofillien, hidroksiëtielteofillien (etofillien), difenhidramienhidrochloried, ammoniumchloried, natriumsitraat of enige van die ander bestanddele van ALCOPHYLLEX.
- Indien u baba lewendig gebore is voordat 37 weke van swangerskap voltooi is.
- Indien u porfirie het ('n groep seldsame afwykings van sekere ensieme).
- Indien u 'n ernstige longsiekte het (byvoorbeeld asma-aanvalle).
- Indien u aan lewer- of nierprobleme ly.
- Indien u 'n opbou van suur in die liggaam het as gevolg van niersiekte of nierversaking of wanneer die longe nie al die koolstofdioksied wat die liggaam produseer kan verwyder nie.
- Indien u aan 'n elektrolietwanbalans ly, bv. hipokalsemie (lae vlak van kalsium in die bloed).
- Indien u hipochloorhidrie het (produksie van maagsuur in die maag is afwesig of laag).
- Indien u aan epilepsie ly (stuipaanvalle), of dit in die verlede gehad het.
- Moenie ALCOPHYLLEX aan babas of kinders onder die ouderdom van 2 jaar gee nie.
- Indien u monoamienoksidase-inhibeerders (MAOIs) (antidepressante) saam met ALCOPHYLLEX neem.
- Onlangse hartaanval/ akute aanvang van 'n hartklop wat die normale rustempo oorskry
- Gebruik ALCOPHYLLEX met sekere antihistamiene, d.i. efedrien.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met ALCOPHYLLEX:

- Indien u 'n aanhoudende hoes het wat langer as 'n week aanhou, raadpleeg asseblief 'n dokter.
- Indien u 'n maagseer het.
- Indien u 'n ooraktiewe tiroïedklier het.
- Indien u hoë bloeddruk, onreëlmatige hartklop of enige hartsiekte het.
- Indien u bejaard is.
- Indien u aan alkoholisme ly.
- Indien u gloukoom het ('n toestand van die oog wat tot blindheid lei), urinêre retensie (onvermoë om te urineer), of prostaathipertrofie (vergroting van die prostaatklier).
- Indien u 'n tipe siekte het wat gekenmerk word deur 'n skielike aanvang van koors, wat 'n toename in interne liggaamstemperatuur tot vlakke bo normaal is (akute koorssiekte).
- Indien u lae vlakke van suurstof in u liggaamsweefsel het (ernstige hipoksie).
- Indien u 'n toestand het wat veroorsaak dat die regterkant van die hart faal (*cor pulmonale*).
- Indien u 'n toestand het wat veroorsaak word deur te veel vloeistof in die longe (akute pulmonale edeem).
- Indien u chroniese longsiekte, lewer- en nierprobleme het.
- Indien u hoë dosisse difenhidramien-bevattende medisyne gebruik, soos ALCOPHYLLEX, dit kan lei tot ernstige hartprobleme, stuipaanvalle, koma en die dood.
- Die bejaarde pasiënte is veral geneig tot duiseligheid, sedasie, verwarring, hipotensie (lae bloeddruk) en anticholinergiese effekte (droë mond, versteurde visie, droë oë, hardlywigheid of urinêre probleme)
- Kan opgewondenheid veroorsaak, veral by kinders.
- ALCOPHYLLEX is nie geskik vir kinders wat aan diabetes mellitus ly nie.

Ander medisyne en ALCOPHYLLEX

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Die gebruik van ALCOPHYLLEX met ander *xantiene* (bv. aminofillien) moet vermy word.
- Die volgende medisyne kan veroorsaak dat ALCOPHYLLEX langer in die liggaam bly en verhoog sodoende die moontlikheid van newe-effekte; *allopurinol* (om jig te behandel), simetidien (gebruik om die simptome van sooibrand te verlig), *propranolol*, *verapamiel* (word gebruik om hartprobleme te behandel), *eritromisien*, *tetrasiklien*, *kinolone* (antibiotika), *isoniasied* (gebruik in die behandeling van TB), *disulfiraam* (om alkoholisme te behandel), *fluvoksamien* (gebruik om depressie te behandel), *interferon alfa* (gebruik in die behandeling van sommige kankers), *orale voorbehoedmiddels* (geboortebeperkingspil), *kafeïen*, *tiabendasool* (gebruik om wurms te behandel), *BCG-inenting* en *griep-inenting*.
- Die volgende medisyne kan die doeltreffendheid van ALCOPHYLLEX verminder; *fenitoïen* en ander stuiptrekking-middels (wat gebruik word om epilepsie te behandel), *ritonavir* (gebruik in die behandeling van MIV), *rifampisien* (gebruik in die behandeling van TB), *sulfinpirasoon* (gebruik om jig te behandel) en *sigaretrook*.
- ALCOPHYLLEX kan hipokalemie veroorsaak (lae konsentrasie van kalium in die bloed) indien dit gebruik word saam met *beta$_2$-agoniste* (gebruik in die behandeling van asma), *kortikosteroïede* (word gebruik om verskeie toestande te behandel, insluitend artritis, rumatiek, allergiese toestande, en sekere velsiektes), en *diuretika* (watertablette).
- ALCOPHYLLEX kan die newe-effekte van *litium* (gebruik in die behandeling van depressie), *halotaan*, *ketamien* en *adenosien* verhoog wanneer dit saam geneem word.
- Daar is 'n moontlikheid dat ALCOPHYLLEX verhoogde newe-effekte kan veroorsaak wanneer dit saam met *monoamienoksidase-remmers* (gebruik in die behandeling van depressie) gebruik word.
- Die effek dat ALCOPHYLLEX u lomerig laat voel, kan verhoog word indien dit gelyktydig saam met

hipnotika (bv. flunitrasepam), *alkohol*, *barbiturate* (bv. fenobarbitaal) en *kalmeermiddels* (bv. zolpidem) gebruik word.

- ALCOPHYLLEX kan die waarskuwingstekens van skade wat veroorsaak word deur *aminoglikosied antibakteriese middels* (bv. gentamisien) verbloem.
- ALCOPHYLLEX kan met die resultate van veltoetse inmeng en moet gestaak word ‘n paar dae voor die toetse.
- ALCOPHYLLEX kan die absorpsie van aluminium vanuit die spysverteringskanaal verhoog.
- Xantien-bevattende drankies (bv: tee, koffie, kakao) kan inmeng met sommige laboratoriumtoetse vir teofillien.

Neem ALCOPHYLLEX met kos en drank:

ALCOPHYLLEX moet saam met kos geneem word om moontlike newe-effekte te verminder.

Swangerskap, borsvoeding en vrugbaarheid

Veiligheid vir gebruik tydens swangerskap en borsvoeding is nie vasgestel nie.
Indien u swanger is of borsvoed, dink u is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat ALCOPHYLLEX geneem word.

Bestuur en gebruik van masjinerie

ALCOPHYLLEX kan lei tot lomerigheid en verswakte konsentrasie. U moet dus nie 'n motorvoertuig bestuur, gevaarlike masjinerie gebruik of gevaarlike hoogtes uitklim nie, aangesien verswakte besluitneming tot ongelukke kan lei.

ALCOPHYLLEX bevat sukrose:

Indien u dokter u ingelig het dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u

dokter voordat u ALCOPHYLLEX neem.

ALCOPHYLLEX bevat alkohol:

Hierdie medisyne bevat 0,021 mg alkohol (etanol) in elke 5 mL wat gelykstaande is aan 0,5 % *v/v*.

Die klein hoeveelheid alkohol in hierdie medisyne sal nie merkbare effekte veroorsaak nie.

ALCOPHYLLEX bevat natrium:

Hierdie medisyne bevat 50 mg natrium (hoofkomponent van kook/tafelsout) in elke 5 mL of 10 mg/mL stroop. Dit is gelykstaande aan 0,5 % van die aanbevole maksimum daaglikse dieet-inname van natrium vir 'n volwassene.

3. Hoe om ALCOPHYLLEX te neem

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Moenie die aanbevole dosis oorskry nie. Neem ALCOPHYLLEX altyd presies soos beskryf in hierdie biljet of soos u dokter, apteker of verpleegkundige u ingelig het. U moet u dokter of apteker raadpleeg indien u onseker is. Indien u die indruk kry dat ALCOPHYLLEX te swak of te sterk is, raadpleeg u dokter of apteker. Indien dit lyk asof ALCOPHYLLEX nie so goed soos gewoonlik werk nie, raadpleeg so gou as moontlik u dokter. U borsprobleem kan erger word, en u sal dalk ander of bykomende medisyne nodig hê. Moenie ekstra of hoër dosisse ALCOPHYLLEX neem nie, tensy u dokter u so beveel.

Die algemene dosis vir *volwassenes*: 2 tot 3 medisynemate (10 tot 15 mL) elke vier uur.
Die algemene dosis vir *kinders van 2 tot 6 jaar*: ½ tot 1 medisynemaat (2,5 tot 5 mL) elke vier uur.
Die algemene dosis vir *kinders van 7 tot 12 jaar:* 1 tot 2 medisynemate (5 tot 10 mL) elke vier uur.
Slegs mondelinge toediening.

Skud die bottel voor gebruik.

Dosisse moet mondelings geneem word met 'n voldoende hoeveelheid vloeistof (halwe tot een glas)

Indien u meer ALCOPHYLLEX neem as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van die twee beskikbaar is nie, soek hulp by die naaste hospitaal of gifhulpsentrum. U kan naarheid, braking, diarree, vinnige asemhaling, kortasem, spierswakheid, bewing, rusteloosheid, hoë of lae bloeddruk, slaperigheid, onreëlmatige hartklop, koma en stuiptrekkings ervaar.

Indien u vergeet om ALCOPHYLLEX te neem

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte

ALCOPHYLLEX kan newe-effekte hê.

Nie alle newe-effekte wat vir ALCOPHYLLEX aangemeld is, word in hierdie biljet ingesluit nie.

Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u ALCOPHYLLEX neem, raadpleeg asseblief u gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, staak gebruik van ALCOPHYLLEX en lig u dokter onmiddellik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak;

- veluitslag of jeukerigheid;
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige allergiese reaksie op ALCOPHYLLEX gehad. U sal dalk dringend mediese hulp of hospitalisasie benodig.

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- benoude bors,
- veranderinge in die manier waarop u hart klop,
- probleme met urinering of minder urien as wat normaal vir u is,
- versteurde visie,
- spierswakheid,
- nie gekoördineerd wees nie,
- stuiptrekkings.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:

- probleme om aan die slaap te raak,
- gelui in die ore,
- angstig voel,
- rusteloosheid of senuweeagtigheid,
- hoofpyn
- duiseligheid
- verandering in eetlus,

- oormatige kneusplekke of bloeding (wanneer u u vel sny),
- naarheid en braking,
- maagpyne,
- diarree
- hardlywigheid
- droogheid van die mond,
- moegheid
- effense slaperigheid of diep slaap.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat gevind op kan word op SAHPRA se webwerf. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ALCOPHYLLEX te verskaf.

5. Hoe om ALCOPHYLLEX te bêre

BÊRE ALLE MEDIKASIE BUITE BEREIK VAN KINDERS.

Bêre teen of benede 25 °C.

Bêre in die oorspronklike houer. Hou die houer dig toe. Beskerm teen lig.

Moenie gebruik ná die vervaldatum wat op die bottel aangedui word nie.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat ALCOPHYLLEX bevat:

Elke 5 mL bevat:	
Teofillien	16,667 mg
Hidroksiëtielteofillien (etofillien)	1,667 mg
Difenhidramienhidrochloried	6,667 mg
Ammoniumchloried	120 mg
Natriumsitraat	50 mg

Die preserveermiddels metielparabeen 0,1 % *m/v,* propielparabeen 0,015 % *m/v* en alkohol 0,5 % *v/v*.

Ander onaktiewe bestanddele is etanol, karamel-kleurstof [E150], sitroensuurmonohidraat [E330], metielparabeen [E218], propielparabeen [E216], gesuiwerde water, Framboos geursel, sukrose.

Hoe ALCOPHYLLEX lyk en die inhoud van die verpakking

'n Donkerbruin vloeistof met 'n geur van framboos.

100 mL en 200 mL:

Amber PVC-bottel met LLDPE peuter-bestande sluiting.

Amber glasbottel met wit polipropileen sluitingsprop.

Amber PET mediese ronde bottel met wit polipropileen en HDPE kinderbestande opskroef-prop.

2.5 L:

Amber HDPE-houer met wit polipropileen-skroefsluitingsprop met EXPE-voering.

Nie alle verpakkingsgroottes mag gelyktydig bemark word nie.

Houer van Sertifikaat van Registrasie

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