SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE

THEOPHYLLINE ANHYDROUS 200 KIARA (tablets)
THEOPHYLLINE ANHYDROUS 300 KIARA (tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each THEOPHYLLINE ANHYDROUS 200 KIARA sustained release tablets contains: 200 mg theophylline anhydrous.
Each THEOPHYLLINE ANHYDROUS 300 KIARA sustained release tablets contains: 300 mg theophylline anhydrous.
Inactive ingredients: See 6.1 List of excipients
Each THEOPHYLLINE ANHYDROUS 200 KIARA tablet contains sugar (lactose 83 mg).
Each THEOPHYLLINE ANHYDROUS 300 KIARA tablet contains sugar (lactose 124,50 mg).

3. PHARMACEUTICAL FORM

THEOPHYLLINE ANHYDROUS 200 KIARA: white, round, biconvex tablets scored on one side.
THEOPHYLLINE ANHYDROUS 300 KIARA: white, round, flat tablets scored on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of reversible bronchospasm associated with bronchial asthma, chronic bronchitis and emphysema.

4.2 Posology and method of administration

Optimum theophylline serum concentrations lie between 55 to 110 µmol/ℓ (10 to 20 µg/mℓ). The dosage should be individualised as the plasma half-life varies.

The tablets should be ingested 12-hourly and should not be chewed or crushed but should be swallowed whole or halved.

Adults:
300 mg tablets dosage:
- One tablet twice daily. This dose can be gradually increased after three days of treatment, or decreased by half if disturbing side effects occur.

200 mg tablets dosage:
- One tablet twice a day. This dose can be increased by half a tablet (100 mg) twice a day.

Children: The dose per kg should be adjusted according to body mass of the child.

Body Mass	*Initial Dose*		*Daily Dose/kg Body Mass*
12 kg	100 mg	2 x daily	16 mg
15 kg	100 mg	2 x daily	13 mg
20 kg	100 mg	2 x daily	10 mg
30 kg	150 mg	2 x daily	10 mg
40 kg	200 mg	2 x daily	10 mg
50 kg	200 mg	2 x daily	8 mg

The above doses may be increased or decreased by 100 to 200 mg per day if sufficient therapeutic effect is not achieved or if side effects appear.

Recommended maximum daily dose:

Body mass	*Daily dose*
12 kg	300 mg
20 kg	400 mg
30 kg	600 mg
40 kg	800 mg
50 kg or more	900 mg

Serum theophylline levels should be monitored if side effects appear or if higher doses than those recommended, are needed.

4.3 Contraindications

- Acute myocardial infarction.
- Hypersensitivity to THEOPHYLLINE ANHYDROUS KIARA or other xanthine derivatives.

4.4 Special warnings and precautions for use

Caution is recommended when theophylline is used in patients older than 60 years of age. The dosage should be reduced in the elderly and in patients with cardiac failure and impaired hepatic function.
Care should be taken in patients with a history of peptic ulceration.
Use THEOPHYLLINE ANHYDROUS KIARA with caution in patients with hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular disease, acute pulmonary oedema, acute febrile illness, chronic alcoholism, cor pulmonale, hypoxaemia, liver or renal disease and dehydration.

Lactose intolerance:
Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take THEOPHYLLINE ANHYDROUS KIARA.
THEOPHYLLINE ANHYDROUS KIARA contains lactose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

The bronchodilator and toxic effects of THEOPHYLLINE ANHYDROUS KIARA may be enhanced by sympathomimetics and by administration with other xanthines. Smokers may require increased doses.
Concomitant administration with allopurinol, cimetidine, influenza vaccine, propranolol, verapamil, oral contraceptives, disulfiram, thiabendazole, fluvoxamine, fluoroquinolone antibiotics (enoxacin and ciprofloxacin), interferon alpha and macrolide antibiotics (clarithromycin and erythromycin) may result in decreased hepatic theophylline clearance and may necessitate a dosage reduction of THEOPHYLLINE ANHYDROUS KIARA.
Phenytoin and some other anticonvulsants, ritonavir, rifampicin and sulfinpyrazone may increase theophylline clearance, necessitating an increase in dose or dosing frequency.
Concurrent use of lithium with THEOPHYLLINE ANHYDROUS KIARA may increase renal elimination of lithium, thus decreasing its therapeutic effect.
There is a risk of synergistic toxicity if THEOPHYLLINE ANHYDROUS KIARA is given concomitantly with halothane or ketamine, and it may antagonize the effects of adenosine and of competitive neuromuscular blockers.
Concurrent use of THEOPHYLLINE ANHYDROUS KIARA with adenosine may antagonise the cardiovascular effects of adenosine; larger doses of adenosine may be required or alternative therapy should be used.
THEOPHYLLINE ANHYDROUS KIARA may reverse benzodiazepine sedation.

4.6 Fertility, Pregnancy and Lactation

Safety in pregnancy has not been established.
THEOPHYLLINE ANHYDROUS KIARA is distributed into breast milk and is therefore not recommended for breastfeeding mothers.

4.7 Effects on the ability to drive and use machines

THEOPHYLLINE ANHYDROUS KIARA may impair the ability to drive and use machinery.

4.8 Undesirable effects

The side effects commonly encountered with THEOPHYLLINE ANHYDROUS KIARA and its derivatives, irrespective of the route of administration, are gastro-intestinal irritation and stimulation of the central nervous system.

Nervous system disorders:
Less frequent: insomnia, headache, anxiety, restlessness, vertigo and palpitations.
Severe overdosage or idiosyncrasy may also lead to maniacal behaviour, tremor, delirium, convulsions and death. Convulsions may not be preceded by milder symptoms of toxicity.

Cardiac disorders:
Less frequent: tachycardia and hypotension.
Severe overdosage or idiosyncrasy may also lead to tachycardia and tachypnoea.

Vascular disorders:
Severe overdosage or idiosyncrasy may also lead to hyperthermia.

Gastrointestinal disorders:
Less frequent: nausea, vomiting, abdominal pain, gastro-intestinal bleeding and heartburn.
Severe overdosage or idiosyncrasy may also lead to repeated vomiting with resulting electrolyte disturbances and extreme thirst.

Renal and urinary disorders:
Less frequent: increased urination.

General disorders:
Reduced ability to exercise, excessive sweating and metallic taste in the mouth.

4.9 Overdose

CNS stimulation may lead to maniacal behaviour, delirium and convulsions.
Repeated vomiting with extreme thirst, hypotension and hyperthermia have also been reported.
Treatment is symptomatic.
Gastric lavage may be used for overdosage by mouth.
Fluid and electrolyte balance should be maintained with intravenous fluids and sedatives and oxygen given as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological Classification
A 10.2 Bronchodilators
Pharmacotherapeutic group
Xanthines, ATC Code: R03DA04

Theophylline has the ability to relax smooth muscle of the bronchi thereby causing bronchodilation. This occurs especially if the bronchi have been constricted, either experimentally by histamine, or clinically in asthma. It stimulates the central nervous system (CNS), produces a positive chronotropic and inotropic effect, and is also a weak diuretic.

5.2 Pharmacokinetic properties

An individual dosage regimen is recommended because of the variation in plasma half-life of theophylline in various individuals.
Smokers, for instance, have a shorter plasma half-life than non-smokers. Plasma half-life is prolonged in patients suffering from congestive heart failure, hepatic cirrhosis and acute viral infections.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl cellulose, lactose monohydrate, magnesium stearate, povidone and stearic acid.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

48 months when stored in a dry place at or below 25 °C and protected from light.

6.4 Special precautions for storage

This medicine does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottles with polypropylene closures containing LDPE liners, cotton wool wadding, and silica gel sachets as desiccant in pack sizes of 20, 30, 56, 60, 100 or 500 tablets.

White PP securitainers, with white PP closures, foam inserts, and silica gel sachets as desiccant in pack sizes of 20, 30, 56, 60, 100 or 500 tablets.

PVC blister backed with aluminum foil and aluminum aluminum blisters in pack sizes of 20, 30, 56, 60, 100 or 500 tablets.

Patient ready packs - sealed aluminium bags in pack sizes of 20, 30, 56, 60 or 100 tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Kiara Health (Pty) Ltd
72 Steel Road, Spartan, Kempton Park, 1619, South Africa

8. REGISTRATION NUMBERS

THEOPHYLLINE ANHYDROUS 200 KIARA: X/10.2/53
THEOPHYLLINE ANHYDROUS 300 KIARA: X/10.2/54

9. DATE OF FIRST AUTHORISATION

22 April 1991

10. DATE OF REVISION OF TEXT

17 December 2020

African country(ies) registration details:

Country	*Product name*	*Scheduling status (or Category of distribution)*	*Registration number*
Botswana	Theophylline anhydrous 200 Kiara	S2	B9309410
	Theophylline anhydrous 300 Kiara	S2	B9309415
Namibia	Theophylline anhydrous 200 Kiara	NS2	05/10.2/0095
	Theophylline anhydrous 300 Kiara	NS2	05/10.2/0094

ATC Code: R03DA04 – Xanthines

Name and address of manufacturer:
Kiara Health (Pty) Ltd
72 Steel Road
Spartan
Kempton Park
1619
South Africa

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

THEOPHYLLINE ANHYDROUS 200 KIARA (Tablets)
THEOPHYLLINE ANHYDROUS 300 KIARA (Tablets)
Theophylline anhydrous. Contains Sugar (Lactose)

Read all of this leaflet carefully because it contains important information for you.
THEOPHYLLINE ANHYDROUS 200 KIARA and THEOPHYLLINE ANHYDROUS 300 KIARA are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use THEOPHYLLINE ANHYDROUS KIARA carefully to get the best results.
- Keep this leaflet. You may need to read it again.
- Do not share THEOPHYLLINE ANHYDROUS KIARA with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

1. What THEOPHYLLINE ANHYDROUS KIARA is and what it is used for:
- **There are two strengths available: THEOPHYLLINE ANHYDROUS 200 KIARA** sustained release tablets contain 200 mg theophylline anhydrous, which is the active ingredient.
- **THEOPHYLLINE ANHYDROUS 300 KIARA** sustained release tablets contain 300 mg theophylline anhydrous, which is the active ingredient.

THEOPHYLLINE ANHYDROUS KIARA tablets are used to treat patients with bronchospasm that is caused by asthma, chronic bronchitis or emphysema.

Each **THEOPHYLLINE ANHYDROUS 200 KIARA** tablet contains sugar (lactose 83 mg).
Each **THEOPHYLLINE ANHYDROUS 300 KIARA** tablet contains sugar (lactose 124,50 mg).

2. What you need to know before you take THEOPHYLLINE ANHYDROUS KIARA:
Do not take THEOPHYLLINE ANHYDROUS KIARA if you:
- Are hypersensitive/allergic to THEOPHYLLINE ANHYDROUS KIARA or any of the other ingredients.
- Are hypersensitive/allergic to aminophylline or oxtriphylline (also known as xanthine).
- Are pregnant or breastfeeding a baby.
- Had previously suffered from a heart attack.

Warnings and precautions:
Special care should be taken with THEOPHYLLINE ANHYDROUS KIARA:
- If you start or stop smoking.
- If you are older than 60 years.
- If you have problems with your heart or suffer from a heart disease.
- If your liver or kidney function is impaired.
- If you have a stomach ulcer.
- If your thyroid gland is overactive (hyperthyroidism).
- If you have hypertension ("high blood").
- If you suffer from lung problems.
- If you use a lot of alcohol on a regular basis (chronic alcoholism).
- If you are dehydrated (lost a lot of fluid).

Other medicines and THEOPHYLINE ANHYDROUS KIARA:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Please consult your doctor, pharmacist or other healthcare professional for advice if you are taking any of the following medication:
- Allopurinol (medicine for gout).
- Cimetidine (medicine for heartburn or stomach ulcer).
- Oral contraceptives (the "Pill").
- Antibiotics such as clarithromycin, erythromycin or ciprofloxacin.
- Medicine for heart conditions or high blood pressure (such as verapamil or propranolol).
- Flu vaccine.
- Medicine for the treatment of tuberculosis (TB) such as rifampicin or ritonavir.
- Lithium.

Not all the medicines that would interact with THEOPHYLLINE ANHYDROUS KIARA are listed above. Please tell your doctor, pharmacist or healthcare professional about all the medicines you are taking, before you start taking THEOPHYLLINE ANHYDROUS KIARA.

THEOPHYLLINE ANHYDROUS KIARA with food and drink:
- The tablets should be swallowed whole with a glass of water.
- It is recommended that you take this medicine on an empty stomach 30 minutes to 1 hour before a meal, or 2 hours after a meal.
- In some cases your doctor may want you to take this medicine with meals or right after meals to lessen stomach upsets.
- Avoid eating or drinking large amounts of caffeine-containing foods or drinks, such as cocoa, tea, coffee, chocolate and cola drinks.

Pregnancy, breastfeeding and fertility:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice.

The safety of THEOPHYLLINE ANHYDROUS KIARA in pregnant women has not yet been established.

Driving and using machines:
If you suffer from nausea or headaches after using THEOPHYLLINE ANHYDROUS KIARA, make sure that you are well enough to drive or operate machinery, as your ability to react may be impaired.

THEOPHYLLINE ANHYDROUS KIARA contains sugar (Lactose):
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using THEOPHYLLINE ANHYDROUS KIARA.
THEOPHYLLINE ANHYDROUS KIARA contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take THEOPHYLLINE ANHYDROUS KIARA:
Always take THEOPHYLLINE ANHYDROUS KIARA tablets exactly as described in this leaflet or as your doctor, pharmacist or nurse has instructed you. Check with your doctor or pharmacist if you are unsure.
- The tablets should be swallowed whole (not chewed or crushed), with a glass of water and should be taken on an empty stomach.
- It is important to keep taking your medicine for as long as your doctor prescribes them.
- Do not stop taking your medicine without consulting your doctor first.
- The dose might be different for different patients.

THEOPHYLLINE ANHYDROUS 300 KIARA:
Adult dose: One tablet (300 mg) every 12 hours. After three days the dosage can be increased or reduced, by your doctor or healthcare professional.

THEOPHYLLINE ANHYDROUS 200 KIARA:
Adult dose: One tablet (200 mg) every 12 hours. The dose can be increased with half a tablet (100 mg) twice a day, by your doctor or healthcare professional.
Children: The dose is based on body weight and will be determined by your doctor.

If you take more THEOPHYLLINE ANHYDROUS KIARA than you should:
In the event of an overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre immediately. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take THEOPHYLLINE ANHYDROUS KIARA:
If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose and continue with the next dose as before. Do not take two doses at the same time.

4. Possible side effects:
THEOPHYLLINE ANHYDROUS KIARA can cause side effects in some patients.
Not all side effects reported for THEOPHYLLINE ANHYDROUS KIARA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking THEOPHYLLINE ANHYDROUS KIARA please consult your healthcare provider for advice.

Check with your doctor immediately if the following symptom occurs:
- Fast heartbeat.

Inform your doctor as soon as possible if you experience the following symptoms:
- Nausea, vomiting, heartburn and stomach pain.
- Headache.
- Increased urination.
- Nervousness.
- Trouble sleeping.

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 "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of THEOPHYLLINE ANHYDROUS KIARA.

5. How to store THEOPHYLLINE ANHYDROUS KIARA:
- Store at or below 25 °C in a well-closed container.
- Store in the original package to protect from light and moisture.
- Do not store your medicine in the bathroom.
- Do not use THEOPHYLLINE ANHYDROUS KIARA after the expiry date printed on the label, bottle or blister.
- Return the expired medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

6. Contents of the pack and other information:
What THEOPHYLLINE ANHYDROUS KIARA contains:
The active substance is theophylline anhydrous.

The other ingredients are:
Ethyl cellulose, lactose monohydrate, magnesium stearate, povidone and stearic acid.

What THEOPHYLLINE ANHYDROUS KIARA looks like and the contents of the pack:
THEOPHYLLINE ANHYDROUS 200 KIARA is a white, round, biconvex tablet scored on one side.
THEOPHYLLINE ANHYDROUS 300 KIARA is a white, round, flat tablet scored on one side.

The products can be packed in the following packaging and pack sizes:
Amber glass bottles with polypropylene closures containing LDPE liners, cotton wool wadding, and silica gel sachets as desiccant in pack sizes of 20, 30, 56, 60, 100 or 500 tablets.

White PP securitainers, with white PP closures, foam inserts, and silica gel sachets as desiccant in pack sizes of 20, 30, 56, 60, 100 or 500 tablets.

PVC blister backed with aluminum foil and aluminum aluminum blisters in pack sizes of 20, 30, 56, 60, 100 or 500 tablets.

Patient ready packs - sealed aluminum bags in pack sizes of 20, 30, 56, 60 or 100 tablets.

Holder of the Certificate of Registration/ Houer van die Sertifikaat van Registrasie:
Kiara Health (Pty) Ltd, 72 Steel Road, Spartan, Kempton Park, 1619, South Africa

This leaflet was last revised in/ Hierdie blaadjie was laas hersien in: 17 December 2020

Registration numbers/ Registrasienommers:
THEOPHYLLINE ANHYDROUS 200 KIARA: X/10.2/53
THEOPHYLLINE ANHYDROUS 300 KIARA: X/10.2/54

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSTATUS: S2

THEOPHYLLINE ANHYDROUS 200 KIARA (Tablette)
THEOPHYLLINE ANHYDROUS 300 KIARA (Tablette)
Anhidriese teofillien. Bevat Suiker (Laktose)

Lees die hele blaadjie sorgvuldig want dit bevat belangrike inligting vir u.
THEOPHYLLINE ANHYDROUS 200 KIARA en THEOPHYLLINE ANHYDROUS 300 KIARA is sonder 'n doktersvoorskrif vir u beskikbaar om 'n geringe siekte te behandel. Nogtans moet u THEOPHYLLINE ANHYDROUS KIARA versigtig gebruik om die beste resultate te kry.
- Hou hierdie blaadjie. U mag nodig hê om dit weer te lees.
- Moenie THEOPHYLLINE ANHYDROUS KIARA met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

1. Wat THEOPHYLLINE ANHYDROUS KIARA is en waarvoor dit gebruik word:
- **Daar is twee sterktes beskikbaar: THEOPHYLLINE ANHYDROUS 200 KIARA** volgehouevrystellingstablette bevat 200 mg anhidriese teofillien, wat die aktiewe bestanddeel is.
- **THEOPHYLLINE ANHYDROUS 300 KIARA** volgehouevrystellingstablette bevat 300 mg anhidriese teofillien, wat die aktiewe bestanddeel is.

THEOPHYLLINE ANHYDROUS KIARA tablette word gebruik om pasiënte met brongospasma wat deur asma, chroniese brongitis of emfiseem veroorsaak is, te behandel.

Elke **THEOPHYLLINE ANHYDROUS 200 KIARA** tablet bevat suiker (laktose 83 mg).
Elke **THEOPHYLLINE ANHYDROUS 300 KIARA** tablet bevat suiker (laktose 124,50 mg).

2. Wat u moet weet voordat u THEOPHYLLINE ANHYDROUS KIARA neem:
Moenie THEOPHYLLINE ANHYDROUS KIARA neem nie indien u:
- Hipersensitief (allergies) teenoor THEOPHYLLINE ANHYDROUS KIARA of enige van die ander bestanddele is.
- Hipersensitief/allergies vir aminofillien of okstrifillien (ook bekend as xantien) is.
- Swanger is of 'n baba borsvoed.
- Vantevore 'n hartaanval gehad het.

Waarskuwings en voorsorgmaatreëls:
Tref spesiale sorg/Spesiale sorg moet met THEOPHYLLINE ANHYDROUS KIARA getref word:
- Indien u begin of ophou rook.
- Indien u ouer as 60 jaar is.
- Indien u probleme met u hart het of aan'n hartsiekte ly.
- Indien u lewer- of nierfunksie ingekort is.
- Indien u 'n maagseer het.
- Indien u tiroïedklier ooraktief is (hipertiroïdisme).
- Indien u hipertensie het ("hoë bloed").
- Indien u aan longprobleme ly.
- Indien u op 'n gereelde grondslag baie alkohol gebruik (chroniese alkoholisme).
- Indien u ontwater is (baie vloeistof verloor het).

Ander medisyne en THEOPHYLINE ANHYDROUS KIARA:
Lig altyd u professionele gesondheidsorgwerker in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele geneesmiddels in).
Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies indien u enige van die volgende medikasie gebruik:
- Allopurinol (medisyne vir jig).
- Simetidien (medisyne vir sooibrand of maagsere).
- Orale voorbehoeding (die "Pil").
- Antibiotika soos klaritromisien, eritromisien of siprofloksasien.
- Medisyne vir harttoestande of hoë bloeddruk (soos verapamiel of propranolol).
- Griepentstof.
- Medisyne vir die behandeling van tuberkulose (TB) soos rifampisien, ritonavir.
- Litium.

Nie alle medisyne wat met THEOPHYLLINE ANHYDROUS KIARA 'n interaksie kan hê, is hierbo gelys nie. Vertel asseblief vir u dokter, apteker of professionele gesondheidsorgwerker van al die geneesmiddels wat u gebruik voordat u THEOPHYLLINE ANHYDROUS KIARA neem.

THEOPHYLLINE ANHYDROUS KIARA met kos en drank:
- Die tablette moet heel met 'n glas water gesluk word.
- Dit word aanbeveel dat u hierdie medisyne op 'n leë maag 30 minute tot 1 uur voor 'n maaltyd of 2 ure na 'n maaltyd neem.
- In sommige gevalle mag u dokter wil hê dat u hierdie medisyne met maaltye of direk na maaltye neem om maagongesteldheid te verminder.
- Vermy die eet of drink van groot hoeveelhede kafeïenbevattende kos en drankies soos kakao, tee, koffie, sjokolade en koladrankies.

Swangerskap en borsvoeding en fertiliteit:
Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies. Die veiligheid van THEOPHYLLINE ANHYDROUS KIARA is nog nie in swanger vrouens vasgestel nie.

Bestuur en die gebruik van masjiene:
Indien u aan braking of hoofpyne ly nadat u THEOPHYLLINE ANHYDROUS KIARA gebruik het, maak seker dat u gesond genoeg is om te bestuur of masjiene te bedryf, aangesien u vermoë om te reageer ingekort mag wees.

THEOPHYLLINE ANHYDROUS KIARA bevat suiker (Laktose):
Indien u deur u dokter meegedeel is dat u 'n intoleransie vir sekere suikers het, tree met u dokter in verbinding voordat u THEOPHYLLINE ANHYDROUS KIARA gebruik.
THEOPHYLLINE ANHYDROUS KIARA bevat laktosemonohidraat wat 'n effek op die beheer van u bloedsuiker mag hê indien u diabetes mellitus het.

3. Hoe om THEOPHYLLINE ANHYDROUS KIARA te neem:
Neem THEOPHYLLINE ANHYDROUS KIARA tablette altyd presies soos wat dit in hierdie blaadjie beskryf is of soos wat u dokter, apteker of verpleegster u opdrag gegee het. Kontak u dokter of apteker as u nie seker is nie.
- Die tablette moet heel met 'n glas water gesluk word (nie gekou of gebreek nie) en moet op 'n leë maag geneem word.
- Dit is belangrik om u medisyne te neem vir solank u dokter dit voorskryf.
- Moenie ophou om u medisyne te neem sonder om u dokter eers te raadpleeg nie.
- Die dosis mag anders vir verskillende pasiënte wees.

THEOPHYLLINE ANHYDROUS 300 KIARA:
Volwasse dosis: Een tablet (300 mg) elke 12 ure. Na 3 dae kan u dokter of professionele gesondheidsorgwerker die dosis vermeerder of verminder.

THEOPHYLLINE ANHYDROUS 200 KIARA:
Volwasse dosis: Een tablet (200 mg) elke 12 ure. U dokter of professionele gesondheidsorgwerker kan die dosis met 'n halwe tablet (100 mg) twee maal per dag vermeerder.
Kinders: Die dosis is gebaseer op liggaamsgewig en sal deur u dokter bepaal word.

Indien u meer THEOPHYLLINE ANHYDROUS KIARA neem as wat u moes:
In die geval van 'n oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum onmiddellik. Neem hierdie blaadjie en enige oorblywende tablette saam met u sodat die dokter weet wat u geneem het.

Indien u vergeet om THEOPHYLLINE ANHYDROUS KIARA te neem:
Indien u vergeet om 'n dosis te neem, neem dit so gou as wat u onthou. As dit egter amper tyd vir u volgende dosis is, moenie die oorgeslane dosis neem nie en gaan voort met die volgende dosis soos vantevore. Moenie twee dosisse op dieselfde tyd neem nie.

4. Moontlike newe-effekte:
THEOPHYLLINE ANHYDROUS KIARA kan newe-effekte in sommige pasiënte veroorsaak.
Nie alle newe-effekte wat vir THEOPHYLLINE ANHYDROUS KIARA gemeld is, is in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan of indien u enige ongunstige effekte ervaar terwyl u THEOPHYLLINE ANHYDROUS KIARA neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Kontak u dokter onmiddellik indien die volgende simptoom voorkom:
- Vinnige hartklop.

Lig u dokter so gou moontlik in indien u die volgende simptome ervaar:
- Naarheid, braking, sooibrand en maagpyn.
- Hoofpyn.
- Vermeerderde urinering.
- Senuweeagtigheid.
- Probleme om te slaap.

Aanmelding van newe-effekte:
Indien u newe-effekte kry, gesels met u dokter, apteker of verpleegster. U kan newe-effekte ook aan die SARGP via die "6.04 Nadelige Middelreaksie-Aanmeldingsvorm" rapporteer; dit kan aanlyn onder die SARGP se publikasies by https://www.sahpra.org.za/Publications/Index/8 gevind word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veilligheid van THEOPHYLLINE ANHYDROUS KIARA te voorsien.

5. Hoe om THEOPHYLLINE ANHYDROUS KIARA te berg:
- Berg teen of benede 25 ºC in 'n diggeslote houer.
- Bewaar in die oorspronklike verpakking om teen lig en vogtigheid te beskerm.
- Moenie medisyne in die badkamer stoor nie.
- Moenie THEOPHYLLINE ANHYDROUS KIARA na die vervaldatum wat op die etiket, bottel of stulpstrook gedruk is, gebruik nie.
- Besorg alle vervalde medisyne aan u apteker vir veilige wegdoening terug. Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.
- **BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.**

6. Inhoud van die pakkie en ander inligting:
Wat THEOPHYLLINE ANHYDROUS KIARA bevat:
Die aktiewe bestanddeel is anhidriese teofillien.
Die ander bestanddele is:
Etielsellulose, laktosemonohidraat, magnesiumstearaat, povidoon en steariensuur.

Waarna THEOPHYLLINE ANHYDROUS KIARA lyk en die inhoud van die pakkie:
THEOPHYLLINE ANHYDROUS 200 KIARA is 'n wit, ronde, bikonvekse tablet gekeep aan die een kant.
THEOPHYLLINE ANHYDROUS 300 KIARA is 'n wit, ronde, plat tablet gekeep aan die een kant.

Die produkte kan in die volgende verpakkings en verpakkingsgroottes verpak wees:
Amber glasbottels met polipropileensluitings wat LDPE-voerings bevat, watte, en silikajelsakkies as droogmiddel in verpakkingsgroottes van 20, 30, 56, 60, 100 of 500 tablette.

Wit PP-sekuriteitsbewaarders met wit PP-sluitings, skuiminsetsels, en silikajelsakkies as droogmiddel in verpakkingsgroottes van 20, 30, 56, 60, 100 of 500 tablette.

PVC-stulpstrook gerugsteun met aluminiumfoelie en aluminium-aluminiumstulpstroke in verpakkingsgroottes van 20, 30, 56, 60, 100 of 500 tablette.

Pasiëntgereedheidspakke – geseëlde aluminiumsakke in verpakkingsgroottes van 20, 30, 56, 60 of 100 tablette.

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