

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 is 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 health care provider or pharmacist if you need more information or advise.

What is in this leaflet

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

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:

Take special care/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 THEOPHYLLINE 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 health care 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 food or drinks such as cocoa, tea, coffee, chocolate and cola drinks.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care 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 or 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 (100mg) 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 overdose, 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 health care provider for advice.

Check with your doctor immediately if any of the following symptoms 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 in sleeping.

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 “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 containing cotton wool wadding and silica gel sachet 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 sachet as desiccant in pack sizes 20, 30, 56, 60, 100 or 500 tablets.

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

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

Holder of the Certificate of Registration:

Kiara Health (Pty) Ltd

72 Steel Road

Spartan

Kempton Park

1619

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17 December 2020

Registration numbers:

THEOPHYLLINE ANHYDROUS 200 KIARA: X/10.2/53

THEOPHYLLINE ANHYDROUS 300 KIARA: X/10.2/54

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

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South Africa