

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

**S5**

### AMITRIPTYLINE HCl 25 KIARA (TABLETS)

**Amitriptyline hydrochloride**

Contains sugar (lactose 44,76 mg)

#### **Read all of this leaflet carefully before you start taking AMITRIPTYLINE HCl 25 KIARA**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AMITRIPTYLINE HCl 25 KIARA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### **What is in this leaflet**

1. What AMITRIPTYLINE HCl 25 KIARA is and what it is used for
2. What you need to know before you take AMITRIPTYLINE HCl 25 KIARA
3. How to take AMITRIPTYLINE HCl 25 KIARA
4. Possible side effects
5. How to store AMITRIPTYLINE HCl 25 KIARA
6. Contents of the pack and other information

#### **1. What AMITRIPTYLINE HCl 25 KIARA is and what it is used for**

AMITRIPTYLINE HCl 25 KIARA can be used:

- To relieve mental depression.
- In the treatment of bedwetting in children over the age of 11 years, along with other treatments.

## **2. What you need to know before you take AMITRIPTYLINE HCl 25 KIARA**

### **Do not take AMITRIPTYLINE HCl 25 KIARA**

- If you are hypersensitive (allergic) to amitriptyline or any of the other ingredients of Amitriptyline HCl 25 Kiara.
- If you are allergic to any tricyclic antidepressant or to carbamazepine, maprotiline or trazodone.
- If you just had a heart attack.
- If you are pregnant or breastfeeding a baby.
- If you have problems with your liver (e.g., your liver had been damaged).
- If you have a heart disease.
- If you have problems with passing urine.
- If you are using a monoamine oxidase inhibitor (e.g., furazolidone, selegiline, clomipramine or doxepin) or have stopped using it less than 14 days ago.

### **Warnings and precautions**

#### **Take special care with AMITRIPTYLINE HCl 25 KIARA**

##### ***Tell your doctor:***

- If you have to drive, climb dangerous heights or operate dangerous machinery. (Your ability to make decisions might be impaired and this can lead to accidents.)
- If you are going to be treated with electroshock therapy.
- If you develop an allergic skin reaction while using this medicine.
- If you are suffering from diabetes.
- If you have a history of epilepsy (seizures).
- If you have glaucoma (increased pressure in the eye).
- If you are having problems with your prostate gland.
- If you have problems with your blood pressure being too high or too low.
- If you have suicidal tendencies (thoughts of killing yourself).
- If you suffer from constipation.

- If you have problems with your thyroid gland being overactive.

### **Children and adolescents**

This medicine should at all times be kept out of the reach of children. **Overdose of this medicine is very dangerous in young children.**

### **Other medicines and AMITRIPTYLINE HCL 25 KIARA**

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

***Tell your doctor, pharmacist or other healthcare professional if you are taking any of the following medicines:***

- Monoamine oxidase inhibitor (e.g., furazolidone, selegiline, clomipramine or doxepin) or have stopped using it less than 14 days ago.
- Antipsychotics (medicine for mental illness).
- Clonidine (e.g. Catapres).
- Anticoagulants (medicines that makes the blood thinner).
- Cimetidine (medicine used for heartburn or to reduce stomach acid).
- Medicine for overactive thyroid.
- Appetite suppressants (diet pills).
- Medicine for asthma or other breathing problems.
- Medicine for colds, sinus problems, hay fever or allergies.
- Medicine for hypertension (e.g. calcium channel blockers).

Not all the medicines that would interact with AMITRIPTYLINE HCL 25 KIARA are listed above. Please tell your doctor, pharmacist or health care professional about all the medicines you are taking before you start taking AMITRIPTYLINE HCL 25 KIARA.

### **AMITRIPTYLINE HCL 25 KIARA with food and drink**

The tablets should be swallowed whole with a glass of water. It is recommended that you take this medicine with food to lessen the chance of an upset stomach (nausea and vomiting), unless your doctor has advised you to take it on an empty stomach.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine. The safety of AMITRIPTYLINE HCl 25 KIARA in pregnant and breastfeeding women has not yet been established. The use of AMITRIPTYLINE HCl 25 KIARA during the first trimester of pregnancy is not advisable, unless there are very good reasons.

### **Driving and using machines**

AMITRIPTYLINE HCl 25 KIARA may cause some people to become drowsy, dizzy, light-headed or less alert than they are normally. *Do not drive or operate any machinery or do anything else that could be dangerous if you are not alert.*

### **AMITRIPTYLINE HCl 25 KIARA contains lactose**

Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take AMITRIPTYLINE HCl 25 KIARA.

### **3. How to take AMITRIPTYLINE HCl 25 KIARA**

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

Always take AMITRIPTYLINE HCl 25 KIARA exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of AMITRIPTYLINE HCl 25 KIARA is too strong or too weak, talk to your doctor or pharmacist.

The tablets should be swallowed whole with a glass of water and should be taken with or just after meals.

Sometimes this medicine must be taken for several weeks before you begin to feel better. Your doctor should check your progress at regular visits.

**If you are taking this medicine to relieve mental depression:**

The dose will be different for different patients.

***For adults:***

- The usual dose by mouth is 25 mg three times daily.
- If it is necessary to increase the dose, this is best done by gradual increments of 25 mg, up to a maximum of 150 mg (6 tablets) daily.
- Doses of up to 300 mg (12 tablets) daily may be necessary in a few cases, but should only be given to patients in hospital.
- The antidepressant effect may be evident in 4 to 10 days but may take as long as 30 days to develop adequately.
- When a satisfactory response is obtained, a dose of 25 mg two to four times daily is usually sufficient.
- It is appropriate to continue therapy for 3 months or longer to lessen the possibility of reoccurrence of illness.

***For elderly patients:***

- In general, lower dosages are recommended for elderly patients. 50 mg (2 tablets) daily may be satisfactory in elderly patients who may not tolerate higher doses.
- This dose may be given in divided doses or as a single dose, preferably at night.

***For children:***

- AMITRIPTYLINE HCl 25 KIARA are not recommended for depressed patients under 12 years of age.

***In the treatment of bedwetting in children, along with other treatments:***

- Children 11 to 16 years of age may receive 25 to 50 mg of amitriptyline per day at bedtime.

**Never use more than the recommended dose prescribed for children.**

#### **If you take more AMITRIPTYLINE HCL 25 KIARA than you should**

In the event of an overdosage contact your doctor or pharmacist **urgently**. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

You may experience confusion, seizures, disturbed concentration, enlarged pupils, hallucinations, and shortness of breath or troubled breathing.

#### **If you forget to take AMITRIPTYLINE HCL 25 KIARA**

If you missed a dose of this medicine and your dosing schedule is:

- One dose a day at bedtime – Do not take the missed dose in the morning since it may cause side effects like drowsiness which could be disturbing during day time. Instead, consult your doctor.
- More than one dose a day – Take the missed dose as soon as possible. However, if it is almost time for your next dose, skip the missed dose, and go back to your regular dosing schedule. Do not take two doses at the same time.

#### **If you stop taking AMITRIPTYLINE HCL 25 KIARA**

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.**

#### **4. Possible side effects**

Like all medicines, AMITRIPTYLINE HCL 25 KIARA can cause side effects in some patients. The following side effects have been reported.

**Check with your doctor as soon as possible if you experience any of the following side effects:**

***These side effects have been reported less frequently:***

- Blurred vision.
- Confusion.
- Difficulty in speaking or swallowing.
- Fast or irregular heartbeat.
- Hallucinations.
- Problems in urinating.
- Stiffness of arms and legs.
- Nervousness or restlessness.

You may experience other side effects that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

***These side effects have been reported frequently:***

- Dizziness.
- Drowsiness.
- Dryness of mouth and unpleasant taste.
- Weight gain and increased appetite.

***These side effects have been reported less frequently:***

- Diarrhoea.
- Heartburn and/or vomiting.
- Increased sweating.

**Not all side effects reported for AMITRIPTYLINE HCL 25 KIARA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMITRIPTYLINE HCL 25 KIARA, please consult your doctor, pharmacist or other health care professional for advice.**

## **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 AMITRIPTYLINE HCl 25 KIARA.

## **5. How to store AMITRIPTYLINE HCl 25 KIARA**

Store in a dry place at or below 25 °C. Protect from light.

Do not store your medicine in the bathroom.

### **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

Do not use the tablets after the expiry date printed on the container, blister or label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What AMITRIPTYLINE HCl 25 KIARA contains:**

The active substance is 25 mg amitriptyline hydrochloride per tablet.

The other ingredients are croscarmellose sodium, disodium edetate, lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and the colourant Opadry yellow OY-L-32909.

### **What AMITRIPTYLINE HCl 25 KIARA looks like and the contents of the pack**

AMITRIPTYLINE HCl 25 KIARA is a biconvex, yellow, film-coated tablet.

AMITRIPTYLINE HCl 25 KIARA is packed in plastic containers, blisters, sealed aluminium bags or amber glass bottles containing 28, 84 or 100 tablets.

AMITRIPTYLINE HCl 25 KIARA is also packed as 500 tablets in amber glass bottles, plastic containers or foil blisters.

## **Holder of Certificate of Registration**



Kiara Health (Pty) Ltd

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**This leaflet was last revised in**

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**Registration number**

W/1.2/60

**Additional countries registration details:**

<b>Country</b>	<b>Product name</b>	<b>Scheduling status (or Category of distribution)</b>	<b>Registration number</b>
<b>Botswana</b>	AMITRIPTYLINE HCl 25 KIARA	S2	B9308780
<b>Namibia</b>	AMITRIPTYLINE HCl 25 KIARA	NS3	90/1.2/001447

ATC Code: N06CA01 Amitriptyline and psycholeptics

***Name and address of manufacturer:***

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