SCHEDULING STATUS: S5

1. NAME OF THE MEDICINE
AMITRIPTYLINE HCl 25 KIARA (tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each AMITRIPTYLINE HCl 25 KIARA tablet contains: 25 mg amitriptyline hydrochloride.
Contains sugar (lactose 44,76 mg).

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

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
AMITRIPTYLINE HCl 25 KIARA is used in the treatment of depression of the endogenous type. When depression is associated with anxiety, additional therapy may be necessary.
It is also used as adjunctive therapy for nocturnal enuresis in children over the age of 11 years, where organic pathology has been excluded.

4.2 Posology and method of administration
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 daily. Doses of up to 300 mg 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 maintenance dose of 25 mg two to four times daily is usually sufficient. It is appropriate to continue maintenance therapy for 3 months or longer to lessen the possibility of relapse. In general, lower dosages are recommended for elderly patients. A dosage of 50 mg 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.

Use in children:
In view of the lack of experience with the use of this medicine in treating depression in children, it is not recommended for children under 12 years of age suffering from depression.

As adjunctive therapy in enuresis:
In children aged 11 to 16 years, the dose is 25 to 50 mg per day, at bedtime.
The dosages recommended in the treatment of enuresis are low compared with those used in the treatment of depression, even allowing for differences in age and mass. The recommended dose may not be exceeded.

4.3 Contraindications
Contraindicated in the acute phase of myocardial infarction. AMITRIPTYLINE HCl 25 KIARA is contraindicated in patients with liver damage, urinary retention, cardiac failure, recent infarction, or ischaemic heart disease. Tricyclic antidepressants such as AMITRIPTYLINE HCl 25 KIARA should not be given to patients receiving monoamine oxidase inhibitors or for at least 14 days after their discontinuation; severe hypertensive reactions have been reported. These medicines may be given together if the dosages are carefully controlled, preferably in hospital.

4.4 Special warnings and precautions for use
Tricyclic antidepressants such as AMITRIPTYLINE HCl 25 KIARA should at all times be kept out of the reach of children as even small doses may be fatal to them.

At the time of initiation of therapy, patients should be advised not to drive a motor vehicle, climb dangerous heights or operate dangerous machinery, for at least several days. In these situations, impaired decision-making could lead to accidents.

Caution should be exercised with patients suffering from a depressive phase of manic-depressive psychosis, as occasionally hypomania or mania can be precipitated in such patients. Withdraw the medicine if the depression turns into a manic phase.

AMITRIPTYLINE HCl 25 KIARA should be used with caution in patients with a history of epilepsy, glaucoma, prostatic hypertrophy or constipation.

Psychosis may be activated in schizophrenic patients; patients with suicidal tendencies should be carefully supervised during treatment.

Blood sugar concentrations may be altered in diabetic patients.

In patients suffering from cardiac disease, special caution should be observed because of the occasional problems of tachycardia, dysrhythmias, orthostatic hypotension and other unwanted effects on blood pressure, aggravation of conduction disturbances and electrocardiographic abnormalities. Regular cardiological and electrocardiological examination is advised.

Epilepsy and narrow-angle glaucoma may be aggravated.

Withdraw AMITRIPTYLINE HCl 25 KIARA if allergic skin reactions appear.

In elderly male patients suffering from prostatism, urinary retention may be precipitated.

AMITRIPTYLINE HCl 25 KIARA should be used with caution in patients with hyperthyroidism.

Large doses have caused hyperpyrexia, convulsions, circulatory failure and cardiac arrest, respiratory failure, cyanosis, coma and death; deaths have also occurred from agranulocytosis and jaundice.

Lactose intolerance:
AMITRIPTYLINE HCl 25 KIARA contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take AMITRIPTYLINE HCl 25 KIARA.

AMITRIPTYLINE HCl 25 KIARA contains lactose 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
Interactions involving tricyclic antidepressants, including AMITRIPTYLINE HCl 25 KIARA, often result from additive side effects shared by each medicine or from altered metabolism of one medicine by the other. Medicines that inhibit the cytochrome P450 isoenzyme CYP2D6 may produce substantial decreases in AMITRIPTYLINE HCl 25 KIARA metabolism and marked increases in plasma concentrations.

The medicine should usually not be given to patients receiving other central nervous system depressants, e.g. barbiturates, or to patients receiving monoamine oxidase inhibitors - only after a suitable interval has elapsed, for at least 2 weeks after their discontinuation. The medicines may be given together if the dosages are carefully controlled, preferably in hospital. At least 1 to 2 weeks should elapse between withdrawing AMITRIPTYLINE HCl 25 KIARA and starting any medicine liable to provoke a serious reaction (e.g. phenelzine).

The pressor effects of the direct-acting sympathomimetic agents, adrenaline (epinephrine) and noradrenaline (norepinephrine) are enhanced and the use of local anaesthetics containing these vasoconstrictors should be avoided as hypersensitivity reactions may occur.

The simultaneous administration of anticholinergic agents may be dangerous as anticholinergic side effects may be enhanced. The hypotensive effect of certain antihypertensive agents may be reduced.

The effects of AMITRIPTYLINE HCl 25 KIARA are enhanced by thyroid preparations. Concomitant administration of AMITRIPTYLINE HCl 25 KIARA with thyroid hormone therapy may precipitate cardiac arrhythmias.

Cimetidine, methylphenidate, antipsychotics and calcium-channel blockers may reduce the metabolism of AMITRIPTYLINE HCl 25 KIARA leading to the possibility of increased plasma concentrations and accompanying toxicity.

AMITRIPTYLINE HCl 25 KIARA may reduce the antihypertensive effects of betanidine, debrisoquine, guanethidine and clonidine.

Medicines, which prolong the QT interval including antiarrhythmic agents such as quinidine, the antihistamines astemizole and terfenadine, some antipsychotics (notably pimozide and sertindole), cisapride, halofantrine, and sotalol, may increase the likelihood of ventricular arrhythmias when taken with AMITRIPTYLINE HCl 25 KIARA. The problem may be exacerbated where the interacting medicine (such as quinidine or some antipsychotics) also reduces AMITRIPTYLINE HCl 25 KIARA metabolism.

Barbiturates and other enzyme-inducers such as rifampicin and some antiepileptic medicines can increase the metabolism of AMITRIPTYLINE HCl 25 KIARA and may result in lowered plasma concentrations and reduced antidepressant response.

Concurrent administration of AMITRIPTYLINE HCl 25 KIARA and electroshock therapy may increase the hazards of therapy. Such treatment should be limited to patients for whom it is essential. Discontinue this medicine several days before elective surgery, if possible.

Hypertensive reactions, sometimes fatal, have occurred in patients taking a tricyclic antidepressant such as AMITRIPTYLINE HCl 25 KIARA with a monoamine oxidase inhibitor.

Concurrent use of AMITRIPTYLINE HCl 25 KIARA and anticoagulants, coumarin- or indandione-derivates, may increase anticoagulant activity.

4.6 Fertility, pregnancy and lactation
The safety of AMITRIPTYLINE HCl 25 KIARA in pregnancy and lactation has not been established.
Administration is not advised during the first trimester of pregnancy, unless there are compelling reasons for its use.

4.7 Effects on ability to drive and use machines
At the time of initiation of therapy, patients should be advised not to drive a motor vehicle, climb dangerous heights or operate dangerous machinery, for at least several days. In these situations, impaired decision-making could lead to accidents.

Drowsiness or excessive sedation may be caused in certain patients. On the other hand, disorientation and agitation, insomnia and restlessness can occur with normal doses. The risks of central nervous system depression are greater when administered together with other central nervous system depressants, e.g. alcohol, barbiturates.

4.8 Undesirable effects
Blood and the lymphatic system disorders:
Less frequent:
Blood disorders including eosinophilia, bone marrow depression, thrombocytopenia and agranulocytosis have been reported.

Endocrine disorders:
Less frequent:
Changes in blood sugar concentrations may occur. Syndrome of inappropriate antidiuretic hormone secretion (SIADH).

Metabolism and nutrition disorders:
Frequent:
Mass loss or mass gain.

Nervous system disorders:
Frequent:
The main side effects of AMITRIPTYLINE HCl 25 KIARA are due to its anticholinergic actions. These include notably dry mouth, constipation which may lead to paralytic ileus, urinary retention, papillary dilatation with blurred vision and changes in visual accommodation, palpitations and tachycardia. When anticholinergic effects are severe, the medicine should be discontinued or the dosage reduced.

Drowsiness or excessive sedation may be caused in certain patients. On the other hand, disorientation and agitation, insomnia and restlessness can occur with normal doses. The risks of central nervous system depression are greater when administered together with other central nervous system depressants, e.g. alcohol, barbiturates.

Note: Elderly patients are more prone to all these effects and therapy should be initiated at lower than standard doses in the elderly.

Less frequent:
Dizziness, sweating, tremor, ataxia, weakness, fatigue, excitement, hypomania and epileptiform seizure. Extrapyramidal symptoms including speech difficulties may occur.

Cardiac disorders:
Less frequent:
Heartbeat fast, slow or irregular.

Vascular disorders:
Frequent:
Orthostatic hypotension.

Less frequent:
Hypertension.

Gastrointestinal disorders:
Frequent:
Nausea.

Less frequent:
Diarrhoea, vomiting and heartburn.

Hepatobiliary disorders:
Less frequent:
Jaundice.

Skin and subcutaneous tissue disorders:
Less frequent:
Allergic reaction (increased sensitivity to sunlight; skin rash, itching) and alopecia.

Reproductive system and breast disorders:
Less frequent:
Oestrogenic effects may occur with alterations in libido, impotence, gynaecomastia, breast enlargement or galactorrhoea.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose
Overdosage and poisoning may be characterised by central nervous system depression or excitation, severe anticholinergic effects and cardiotoxicity. The following symptoms and signs are characteristic of acute overdosage: drowsiness, restlessness, ataxia, stupor, coma, pyrexia, palpitations, tachycardia, cardiac arrhythmias, hypotension and in severe cases respiratory depression. Epileptiform seizures may occur. Mixed poisoning with other central nervous system depressants is not uncommon.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:
5.1 Pharmacodynamic properties
Pharmacological classification
A 1.2 Psychoanaleptics (antidepressants)
ATC Code
N06AA09 Non-selective monoamine reuptake inhibitors

Amitriptyline is a tricyclic antidepressant. It has anticholinergic and antihistaminic actions and prevents the uptake of catecholamines at adrenergic nerve endings thereby inhibiting their inactivation.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Croscarmellose sodium, disodium edetate, lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and the colourant opadry yellow OY-L-32909.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
24 months if stored in a dry place at or below 25 °C, 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
Securitainers, blisters, sealed aluminium bags or amber glass bottles of 28, 30, 84 or 100 tablets.
Securitainers, blisters or amber glass bottles of 500 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 NUMBER
W/1.2/60

9. DATE OF FIRST AUTHORISATION
23 February 1990

10. DATE OF REVISION OF THE TEXT
18 March 2021

Additional countries registration details:

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

ATC Code: N06AA09
Non-selective monoamine reuptake inhibitors

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

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 11 years and older, 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 health care professional if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor, pharmacist or other health care 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 ususal 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 frequently:
Blurred vision.
Confusion.
Fast or irregular heartbeat.
Problems in urinating.
Nervousness or restlessness.

These side effects have been reported less frequently:
Difficulty in speaking or swallowing.
Hallucinations.
Stiffness of arms and legs.

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

These side effects have been reported less frequently:
Dizziness.
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 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 AMITRIPTYLINE HCl 25 KIARA. Suspected side effects can also be reported directly to the HCR via customercare@kiarahealth.com

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, 30, 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
72 Steel Road
Spartan
Kempton Park
1619
South Africa

This leaflet was last revised in
18 March 2021

Registration number
W/1.2/60

PASIËNTINLIGTINGSBLAADJIE
SKEDULERINGSTATUS: S5

AMITRIPTYLINE HCl 25 KIARA (TABLETTE)
Amitriptilienhidrochloried
Bevat suiker (laktose 44,76 mg)

Lees die hele blaadjie sorgvuldig voordat u begin om AMITRIPTYLINE HCl 25 KIARA te neem.
- Hou hierdie blaadjie. U mag nodig hê om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegsuster of ander gesondheidsorgverskaffer.
- AMITRIPTYLINE HCl 25 KIARA is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit mag hulle skaad, selfs al is hulle simptome dieselfde as u simptome.

Wat in hierdie blaadjie is

1. Wat AMITRIPTYLINE HCl 25 KIARA is en waarvoor dit gebruik word
2. Wat u nodig het om te weet voordat u AMITRIPTYLINE HCl 25 KIARA neem
3. Hoe om AMITRIPTYLINE HCl 25 KIARA te neem
4. Moontlike newe-effekte
5. Hoe om AMITRIPTYLINE HCl 25 KIARA te berg
6. Inhoud van die pakkie en ander inligting

1. Wat AMITRIPTYLINE HCl 25 KIARA is en waarvoor dit gebruik word
AMITRIPTYLINE HCl 25 KIARA kan gebruik word:
- Om geestelike depressie te verlig.
- Vir die behandeling van bednatmaak in kinders van 11 jaar en ouer, saam met ander behandeling.

2. Wat u nodig het om te weet voordat u AMITRIPTYLINE HCl 25 KIARA neem
Moenie AMITRIPTYLINE HCl 25 KIARA neem nie
- Indien u hipersensitief (allergies) vir amitriptilien of enige van die ander bestanddele in AMITRIPTYLINE HCl 25 KIARA is.
- Indien u allergies vir enige trisikliese antidepressant of vir karbamasepien, maprotilien of trasodoon is.
- Indien u sopas 'n hartaanval gehad het.
- Indien u swanger is of 'n baba borsvoed.
- Indien u probleme met u lewer het (bv. as u lewer beskadig is).
- Indien u 'n hartsiekte het.
- Indien u probleme met die passering van urine het.
- Indien u 'n monoamienoksidase-inhibeerder (bv. furasolidoon, selegilien, klomipramien of doksepien) gebruik of die minder as 14 dae gelede gestaak het.

Waarskuwings en voorsorgmaatreëls
Tref spesiale sorg met AMITRIPTYLINE HCl 25 KIARA
Deel u dokter mee:
- Indien u moet bestuur, gevaarlike hoogtes moet klim of gevaarlike masjinerie moet gebruik. (U vermoë om besluite te neem, mag ingekort wees en dit kan tot ongelukke lei).
- Indien u met elektroskokterapie behandel gaan word.
- Indien u 'n allergiese velreaksie ontwikkel terwyl u hierdie medisyne gebruik.
- Indien u aan diabetes ly.
- Indien u 'n geskiedenis van epilepsie (stuipe) het.
- Indien u gloukoom (verhoogde druk in die oog) het.
- Indien u probleme met u prostaatklier het.
- Indien u probleme met u bloeddruk synde dit te hoog of te laag is, het.
- Indien u selfdoodneigings (gedagtes om jouself dood te maak) het.
- Indien u aan hardlywigheid ly.
- Indien u probleme met u skildklier het synde dit ooraktief is.

Kinders en adolessente
Hierdie medisyne moet ten alle tye buite die bereik van kinders gehou word.
Oordosis van hierdie medisyne is baie gevaarlik in jong kinders.

Ander medisyne en AMITRIPTYLINE HCl 25 KIARA
Lig altyd u professionele gesondheidsorgwerker in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele geneesmiddels in).

Lig u dokter, apteker of ander professionele gesondheidsorgwerker in indien u enige van die volgende medisyne neem:
- Monoamienoksidase-inhibeerder (bv. furasolidoon, selegilien, klomipramien of doksepien) of as u minder as 14 dae gelede opgehou het om dit te gebruik.
- Antipsigotika (medisyne vir geestesongesteldheid).
- Klonidien (bv. Catapres).
- Antistolmiddels (medisyne wat die bloed dunner maak).
- Simetidien (medisyne wat gebruik word vir sooibrand en om maagsuur te verminder).
- Medisyne vir 'n ooraktiewe skildklier.
- Eetlusdempers (dieetpille).
- Medisyne vir asma of ander asemhalingsprobleme.
- Medisyne vir verkoue, sinusprobleme, hooikoors of allergieë.
- Medisyne vir hipertensie (bv. kalsiumkanaalblokkers).

Nie alle medisyne wat met AMITRIPTYLINE HCl 25 KIARA 'n interaksie sou kon hê is hierbo gelys nie. Vertel asseblief vir u dokter, apteker of professionele gesondheidsorgwerker van al die geneesmiddels wat u gebruik voordat u begin om AMITRIPTYLINE HCl 25 KIARA te neem.

AMITRIPTYLINE HCl 25 KIARA met kos en drank
Die tablette moet heel met 'n glas water gesluk word. Dit word aanbeveel dat u hierdie medisyne met kos neem om die kanse vir 'n omgekrapte maag (naarheid en braking) te verminder, tensy u dokter u aanbeveel het om dit op 'n leë maag te neem.

Swangerskap en borsvoeding
Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat u hierdie medisyne neem. Die veiligheid van AMITRIPTYLINE HCl 25 KIARA in swanger en borsvoedende vrouens is nog nie vasgestel nie. Die gebruik van AMITRIPTYLINE HCl 25 KIARA gedurende die eerste trimester van swangerskap is nie raadsaam nie, tensy daar baie goeie redes is.

Bestuur en die gebruik van masjiene
AMITRIPTYLINE HCl 25 KIARA mag veroorsaak dat sommige mense lomerig, duiselig, ligh oofdig of minder waaksaam as gewoonlik word. *Moenie bestuur of masjiene bedryf of enige iets anders doen wat gevaarlik mag wees indien u nie helder wakker is nie.*

AMITRIPTYLINE HCl 25 KIARA bevat laktose
Laktose mag 'n effek op die beheer van u bloedsuiker hê indien u diabetes mellitus het.
Pasiënte met die raar oorerflikheidstoestande van laktose-/fruktose- of galaktose-intoleransie moenie AMITRIPTYLINE HCl 25 KIARA neem nie.

3. Hoe om AMITRIPTYLINE HCl 25 KIARA te neem
Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem altyd AMITRIPTYLINE HCl 25 KIARA presies soos wat u dokter u opdrag gegee het. U moet u dokter kontak indien u onseker is. Indien u die indruk het dat die effek van AMITRIPTYLINE HCl 25 KIARA te sterk of te swak is, gesels met u dokter of apteker.

Die tablette moet heel met 'n glas water gesluk word en behoort tydens of net na maaltye geneem te word.

Soms moet hierdie medisyne vir etlike weke geneem word voordat u begin beter voel. U dokter behoort u vordering tydens gereelde besoeke na te gaan.

As u hierdie medisyne neem om geestelike depressie te verlig:
Die dosis sal verskillend vir verskillende pasiënte wees.
Vir volwassenes:
- Die gewone dosis per mond is 25 mg drie maal daagliks.
- Indien dit nodig is om die dosis te vermeerder, kan dit die beste gedoen word in geleidelike inkrementе van 25 mg tot by 'n maksimum van 150 mg (6 tablette) daagliks.
- Dosisse van tot 300 mg (12 tablette) daagliks mag in enkele gevalle nodig wees, maar behoort slegs aan pasiënte in die hospitaal gegee te word.
- Die antidepressiewe effek mag binne 4 tot 10 dae duidelik word, maar mag solank as 30 dae neem om genoegsaam te ontwikkel.
- Wanneer 'n bevredigende respons verkry is, is 'n dosis van 25 mg twee tot vier keer daagliks gewoonlik voldoende.
- Dit is gepas om behandeling vir 3 maande of langer voort te sit om die moontlikheid vir herhaling van die siekte te verminder.

Vir bejaarde pasiënte:
- Oor die algemeen word laer doserings vir bejaarde pasiënte aanbeveel. 50 mg (2 tablette) daagliks mag voldoende wees in bejaarde pasiënte wat nie hoër dosisse mag tolereer nie.
- Hierdie dosis mag in verdeelde dosisse of as 'n enkeldosis, verkieslik snags, gegee word.

Vir kinders:
- AMITRIPTYLINE HCl 25 KIARA word nie vir depressiewe pasiënte onder 12 jaar van ouderdom aanbeveel nie.

Vir die behandeling van bednatmaak in kinders, saam met ander behandeling:
- Kinders 11 tot 16 jaar van ouderdom mag 25 tot 50 mg amitriptilien per dag met slaaptyd ontvang.

Moet nooit meer as die aanbevole dosis voorgeskryf vir kinders gebruik nie.

Indien u meer AMITRIPTYLINE HCl 25 KIARA neem as wat u moes
In die geval van oordosering, kontak u dokter of apteker **dringend**. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem hierdie blaadjie en enige oorblywende tablette saam met u sodat die dokter weet wat u geneem het.
U mag verwarring, stuipe, versteurde konsentrasie, vergrote pupille, hallusinasies en kortasemheid of moeisame asemhaling ondervind.

Indien u vergeet om AMITRIPTYLINE HCl 25 KIARA te neem
Indien u 'n dosis van hierdie medisyne oorgeslaan het en u doseringskedule is:
- Een dosis per dag met slaaptyd – Moenie die oorgeslane dosis in die oggend neem nie, aangesien dit newe-effekte soos lomerigheid kan veroorsaak wat steurend gedurende die dag mag wees. Raadpleeg eerder u dokter.
- Meer as een dosis per dag – Neem die oorgeslane dosis so gou as moontlik. As dit egter amper tyd vir u volgende dosis is, slaan die vergete dosis oor en keer na u gewone doseringskedule terug. Moenie twee dosisse op dieselfde tyd neem nie.

As u stop om AMITRIPTYLINE HCl 25 KIARA te neem
Dit is belangrik om aan te hou om u medisyne te neem vir solank as wat u dokter dit voorskryf. **Moenie ophou om u medisyne te neem sonder om u dokter eers te raadpleeg nie.**

4. Moontlike newe-effekte
Soos alle medisyne kan AMITRIPTYLINE HCl 25 KIARA newe-effekte in sommige pasiënte veroorsaak. Die volgende newe-effekte is gemeld.

Kontak u dokter so gou as moontlik indien u enige van die volgende newe-effekte ondervind:
Hierdie newe-effekte is dikwels gemeld:
Dowwe visie.
Verwarring.
Vinnige of onreëlmatige hartklop.
Probleme met urinering.
Senuweeagtigheid of rusteloosheid.

Hierdie newe-effekte is minder dikwels gemeld:
Moeisame spraak of sluk.
Hallusinasies.
Styfheid van die arms en bene.

U mag ander newe-effekte ervaar wat gewoonlik nie mediese aandag benodig nie. Hierdie newe-effekte mag gedurende behandeling weggaan soos wat u liggaam by die medisyne aanpas. Kontak egter u dokter indien enige van die volgende newe-effekte voortduur of lastig is:

Hierdie newe-effekte is dikwels gemeld:
Lomerigheid.
Droë mond of onaangename smaak.
Gewigstoename en verhoogde eetlus.

Hierdie newe-effekte is minder dikwels gemeld:
Duiseligheid.
Diarree.
Sooibrand en/of braking.
Verhoogde sweet.

Nie alle newe-effekte wat vir AMITRIPTYLINE HCl 25 KIARA gemeld is, is in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan of indien u enige ongunstige effekte ervaar terwyl u AMITRIPTYLINE HCl 25 KIARA neem, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Aanmelding van newe-effekte
Indien u newe-effekte kry, gesels met u dokter, apteker of verpleegster. U kan newe-effekte ook aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting-platform (who-umc.org) gevind op die SAHPRA-webwerf. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van AMITRIPTYLINE HCl 25 KIARA te voorsien. Vermoedelike newe-effekte kan ook direk aan die HCR via customercare@kiarahealth.com gerapporteer word.

5. Hoe om AMITRIPTYLINE HCl 25 KIARA te berg
Berg in 'n droë plek teen of benede 25 °C. Beskerm teen lig.
Moenie u medikasie in die badkamer bewaar nie.
BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
Moenie die tablette na die vervaldatum wat op die houer, stulpstrook of etiket gedruk is, gebruik nie.
Besorg alle ongebruikte medisyne aan u apteker terug.
Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Wat AMITRIPTYLINE HCl 25 KIARA bevat:
Die aktiewe bestanddeel is 25 mg amitriptilienhidrochloried per tablet.
Die ander bestanddele is natriumkroskarmellose, dinatriumedetaat, laktose, magnesiumstearaat, mikrokristallyne sellulose, natriumstyselglikolaat en die kleurstof opadry-geel OY-L-32909.

Waarna AMITRIPTYLINE HCl 25 KIARA lyk en inhoud van die pakkie
AMITRIPTYLINE HCl 25 KIARA is 'n bikonvekse, geel, filmbedekte tablet.
AMITRIPTYLINE HCl 25 KIARA is verpak in plastiekhouers, stulpstroke, geseëlde aluminiumsakke of amberkleurige glasbottels met 28, 30, 84 of 100 tablette.
AMITRIPTYLINE HCl 25 KIARA is ook verpak as 500 tablette in amberkleurige glasbottels, plastiekhouers of stulpstroke.

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