SCHEDULING STATUS: S3

1. NAME OF MEDICINE
ATENOLOL 50 KIARA (50 mg, film-coated tablet)
ATENOLOL 100 KIARA (100 mg, film-coated tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ATENOLOL 50 KIARA film-coated tablet contains atenolol 50 mg.
Each ATENOLOL 100 KIARA film-coated tablet contains atenolol 100 mg.

ATENOLOL 50 KIARA: Each film-coated tablet contains 63,5 mg lactose.
ATENOLOL 100 KIARA: Each film-coated tablet contains 127 mg lactose.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
ATENOLOL 50 KIARA: White, round, biconvex, film-coated tablets.

ATENOLOL 100 KIARA: Orange, round, biconvex, film-coated tablets, scored on one side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Hypertension and management of angina pectoris.

4.2 Posology and method of administration
In hypertension: 100 mg daily as a single dose.
In angina pectoris: 50 to 100 mg daily given as a single or divided doses.

4.3 Contraindications
ATENOLOL KIARA should not be used:
- In the presence of second- or third-degree heart block.
- In congestive cardiac failure.
- With verapamil, and neither should be administered within several days of discontinuing the other.
- In metabolic acidosis (e.g., in diabetes mellitus).
- After prolonged fasting.

Particular caution should be exercised with patients suffering from asthma, bronchitis, chronic respiratory diseases and bradycardia (less than 50 beats per minute), peripheral vascular diseases and Raynaud's phenomenon.
The normal dose should be reduced in elderly patients or in patients with renal dysfunction.
In the peri-operative period, it is generally unwise to reduce the dosage to which the patient is accustomed, as there may be danger of aggravation of angina pectoris or hypertension. A patient's normal tachycardiac response to hypovolaemia or blood loss may be obscured during or after surgery. Particular caution should be taken in this regard.

4.4 Special warnings and precautions for use
If ATENOLOL KIARA and clonidine are given concurrently, clonidine should not be discontinued until several days after the withdrawal of atenolol as severe rebound hypertension may occur.
Congestive cardiac failure and marked bradycardia may occur.
ATENOLOL KIARA may mask the symptoms of hyperthyroidism.
Concomitant administration with hypoglycaemic agents, phenothiazines and various anti-arrhythmic agents can have life-threatening consequences.

Digitalisation of patients receiving long-term beta blocker therapy may be necessary if congestive cardiac failure is likely to develop. This combination can be considered despite the potentiation of negative chronotropic effects of the two medicines. Careful control of dosages and of the individual patient's response (and notably pulse rate) is essential in this situation.
Patients with phaeochromocytoma usually require concomitant treatment with an alpha-adrenergic blocker.
Treatment should not be discontinued abruptly, as it may cause exacerbation of angina pectoris in patients suffering from ischaemic heart disease. Discontinuation should be gradual and patients should be advised to limit the extent of their physical activity during this period.
ATENOLOL KIARA may mask the symptoms of hypoglycaemia in patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction
In anaesthesia, the anaesthetist should be made aware of ATENOLOL KIARA therapy in patients.
The effects of ATENOLOL KIARA may be enhanced by adrenergic neurone blocking agents such as guanethidine and reserpine. The effect may be antagonised by beta-adrenoceptor stimulants (e.g., isoprenaline).
The hypotensive effect of ATENOLOL KIARA may be dangerously reversed and the peripheral vasoconstrictor effects enhanced by agents with alpha-adrenoceptor stimulating properties such as noradrenaline and adrenaline.
The hypotensive effect may be enhanced by diuretics.
The effects of myocardial depressants such as lignocaine, procainamide, quinidine, phenytoin, and medicines interfering with calcium transport may be enhanced.

4.6 Fertility, pregnancy and lactation
Pregnancy:
The administration of beta blockers to pregnant mothers shortly before birth or during labour has resulted in new-born infants being born hypotonic, collapsed and hypoglycaemic.

Lactation:
Atenolol is excreted into breast milk. Neonates born to mothers who are receiving ATENOLOL KIARA at parturition or while breastfeeding may be at risk of hypoglycaemia and bradycardia.

4.7 Effects on ability to drive and use machines
ATENOLOL KIARA has no or negligible influence on the ability to drive and use machines. However, undesirable effects may occur (e.g., allergic reaction, dizziness, convulsions), which may influence the ability to drive and use machines (see section 4.8).

4.8 Undesirable effects
a) Summary of safety profile
Adverse reactions are more common in patients with renal decompensation
b) Tabulated summary of adverse reactions

Blood and lymphatic system disorders
Frequency unknown:* Blood disorders
(*Cannot be reliably estimated from available data.)

Immune system disorders
Frequency unknown: Allergic reactions

Endocrine disorders
Frequency unknown: Hypoglycaemia

Metabolism and nutrition disorders
Frequency unknown: Metabolic disturbances, weight gain, fluid retention

Psychiatric disorders:
Frequency unknown: A variety of neuropsychiatric disorders may occur, ranging from vague fatigue and malaise, sleeplessness, vivid dreams and nightmares, to overt psychosis; also, insomnia, lassitude, fatigue, depression, hallucinations

Nervous system disorders
Frequency unknown: Confusion, dizziness, paraesthesias

Eye disorders
Frequency unknown: Dry eyes, disturbances of vision

Ear and labyrinth disorders
Frequency unknown: Transient hearing loss

Vascular disorders
Frequency unknown: Cold extremities, hypotension, paradoxical hypertension, exacerbation of peripheral vascular disease, or the development of Raynaud's phenomenon, severe peripheral vascular disease and even peripheral gangrene may occur

Respiratory, thoracic, and mediastinal disorders
Frequency unknown: Bronchoconstriction, particularly in patients suffering from asthma, bronchitis, or other pulmonary diseases

Gastrointestinal disorders
Frequency unknown: Nausea, diarrhoea, dry mouth and/or stomatitis, gastrointestinal disturbances

Skin and subcutaneous tissue disorders
Frequency unknown: Skin rashes, alopecia

Musculoskeletal and connective tissue disorders
Frequency unknown: Myopathies, skeletal muscle weakness

Reproductive system and breast disorders
Frequency unknown: Impaired sexual function, impotence

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 asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose
Overdosage may produce bradycardia and severe hypotension and bronchospasm. Heart failure may be produced in certain individuals.
Patients with mild overdosage should be observed for at least 4 hours, as apnoea and cardiovascular collapse may appear suddenly.
Gastric lavage should be performed within 4 hours of suspected overdosage.
Activated charcoal is necessary in severe overdosage.
Atropine may be used to treat bradycardia. If the response is inadequate, glucagon may be given intravenously. Alternatively, dobutamine or isoprenaline may be used for the management of hypotension. Large doses of isoprenaline may be required to counteract the beta-blockade. Transvenous cardiac pacing may be required for severe bradycardia.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological classification: A 5.2 Adrenolytics (sympatholytics)
ATC Code: C07AB03 Beta blocking agents, selective

Atenolol is a hydrophilic beta blocker. It reduces cardiac activity by diminishing or preventing sympathetic beta-adrenoceptor stimulation.
It is classified as cardio-selective and has no intrinsic sympathomimetic activity and membrane stabilising properties.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Carnauba wax, colloidal silicon dioxide (Aerosil), crospovidone, ethanol 96 %, isopropyl alcohol, lactose, magnesium stearate, microcrystalline cellulose (Avicel PH 102), povidone K30, sodium starch glycolate (explotab), talc purified.
ATENOLOL 50 KIARA: Opadry white Y-1-7000 (methocel E5 premium EP, titanium dioxide, polyethylene glycol 4000).
ATENOLOL 100 KIARA: Opadry orange OY-L-33047 (H.P.M.C 15 cps, lactose, titanium dioxide, polyethylene glycol 4000, sunset yellow lake, quinoline yellow lake).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
48 months.

6.4 Special precautions for storage
Store in a dry place at or below 25 °C and protect from light.
KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container
ATENOLOL 50 KIARA is supplied in blisters, amber glass containers, sealed aluminium bags or securitainers with 28, 30 or 100 tablets.
Blisters, amber glass containers or securitainers with 500 tablets.

ATENOLOL 100 KIARA is supplied in blisters, amber glass containers, sealed aluminium bags or securitainers with 28, 30 or 100 tablets.
Blisters, amber glass containers or securitainers with 500 tablets.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Kiara Health (Pty) Ltd
72 Steel Road, Spartan
Kempton Park, 1619 South Africa

8. REGISTRATION NUMBER(S)
ATENOLOL 50 KIARA: X/5.2/388
ATENOLOL 100 KIARA: X/5.2/389

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
23 January 1991

10. DATE OF REVISION OF THE TEXT
6 December 2022

Additional countries registration details:

Country	*Product name*	*Scheduling status (or Category of distribution)*	*Registration number*
Botswana	Atenolol 50 Kiara	S2	B9308810
	Atenolol 100 Kiara	S2	B9308815
Namibia	Atenolol 50 Kiara	NS2	04/5.2/1462
	Atenolol 100 Kiara	NS2	04/5.2/0675
Mauritius	Atenolol 50 Kiara		R2975/02/14
	Atenolol 100 Kiara		R2974/02/14

ATC Code: C07AB03 - Beta blocking agents, selective

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

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS: S3
ATENOLOL 50 KIARA (50 mg, film-coated tablets)
ATENOLOL 100 KIARA (100 mg, film-coated tablets)
Atenolol
Each ATENOLOL 50 KIARA film-coated tablet contains sugar (lactose 63,5 mg).
Each ATENOLOL 100 KIARA film-coated tablet contains sugar (lactose 127 mg).

Read all of this leaflet carefully before you start taking ATENOLOL KIARA
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- ATENOLOL 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.

1. What ATENOLOL KIARA is and what it is used for
ATENOLOL KIARA contains the active substance atenolol.
Atenolol belongs to a group of medicines called adrenolytics (sympatholytics).
ATENOLOL KIARA is used for the treatment of high blood pressure and angina pectoris (chest pain due to a decrease in blood supply to the heart).

2. What you need to know before you take ATENOLOL KIARA
Do not take ATENOLOL KIARA:
- If you are hypersensitive (allergic) to atenolol or any of the other ingredients of ATENOLOL KIARA (listed in section 6).
- If you have heart block or have a history of cardiac failure.
- If you are on verapamil treatment for your heart.
- If you suffer from metabolic acidosis (the rate of acid production is higher than the acid excretion rate), for instance in diabetes mellitus.
- If you have not eaten for a prolonged period of time.
- If you suffer from asthma, bronchitis, bradycardia (slow heart rate), Raynaud's phenomenon (skin disease) or any chronic respiratory disease.

Warnings and precautions
Take special care with ATENOLOL KIARA:
- Tell your doctor if you are on clonidine treatment (high blood pressure treatment).
- Atenolol is excreted into breast milk. Tell your doctor if you are breast feeding.
- Do not stop taking ATENOLOL KIARA abruptly. Consult your doctor before you stop taking your tablets.
- Inform your doctor of your treatment with ATENOLOL KIARA before surgery that requires anaesthesia.
- The normal dose should be reduced in elderly patients or in patients with renal dysfunction.

Other medicines and ATENOLOL KIARA
Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Concurrent use of ATENOLOL KIARA with antidiabetic medication, heart medication or phenothiazines may be life-threatening.

The following medication may enhance the effects of atenolol:
- guanethidine and reserpine
- diazoxide
- clonidine
- diuretics (high blood pressure medication, e.g., furosemide).

Noradrenaline and adrenaline can dangerously reverse the effects of ATENOLOL KIARA and concomitant use is not recommended.

ATENOLOL KIARA can enhance the effects of lignocaine, procainamide, quinidine and phenytoin.

Inform your doctor if you are on allergen immunotherapy and before you have allergenic extract skin testing done.

The use of halothane, chloroform, cyclopropane, enflurane, isoflurane, methoxyflurane and trichloroethylene (anaesthetics) with ATENOLOL KIARA can lead to a decrease in heart rate and low blood pressure.

Theophylline and aminophylline (asthma treatment) may interfere with the efficacy of ATENOLOL KIARA.

ATENOLOL KIARA with food, drink, and alcohol
You may take ATENOLOL KIARA with meals or on an empty stomach.

Pregnancy, breastfeeding, and fertility
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 provider for advice before taking ATENOLOL KIARA.
Do not take ATENOLOL KIARA if you are pregnant or breastfeeding.

Driving and using machines
ATENOLOL KIARA can cause side effects, such as dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how ATENOLOL KIARA affects you.

ATENOLOL KIARA contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking ATENOLOL KIARA.

3. How to take ATENOLOL KIARA
Do not share medicines prescribed for you with any other person.

Always take ATENOLOL KIARA exactly as your doctor has instructed you. Check with your doctor if you are unsure.

In hypertension: 100 mg daily as a single dose.
In angina pectoris: 50 mg to 100 mg daily given as a single or divided doses.

The normal dose should be reduced in elderly patients or in patients with renal dysfunction.

If you have the impression that the effect of ATENOLOL KIARA is too strong or too weak, talk to your doctor or pharmacist.

If you take more ATENOLOL KIARA than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ATENOLOL KIARA
Do not take a double dose to make up for forgotten individual doses. Continue to take the next tablet at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

4. Possible side-effects
ATENOLOL KIARA can have side effects.
Not all side-effects reported for ATENOLOL KIARA are included in this leaflet. Should your general health worsen while taking ATENOLOL KIARA, please consult your healthcare provider for advice.

The following side-effects have been reported:
- Dizziness or light headedness when getting up, difficulty in breathing.
- Swelling of ankles, feet or lower legs, irregular heartbeat, cold hands and feet and chest pain.
- Skin rash, red and scaling (or crusting) skin.
- Back and joint pain.
- Unusual bruising or bleeding.
- Decreased sexual ability, trouble in sleeping and unusual tiredness.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions 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 ATENOLOL KIARA.

5. How to store ATENOLOL KIARA
Store in a dry place at or below 25 ºC and protect from light.
STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.
Do not use the tablets after the expiry date printed on the blister and container.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).
Keep blisters in the outer carton until required for use.

6. Contents of the pack and other information
What ATENOLOL KIARA contains
- The active substance is atenolol.

Each ATENOLOL 50 KIARA film-coated tablet contains atenolol 50 mg.
Each ATENOLOL 100 KIARA film-coated tablet contains atenolol 100 mg.
- The other ingredients are:

Carnauba wax, colloidal silicon dioxide (Aerosil), crospovidone, ethanol 96 %, isopropyl alcohol, lactose, magnesium stearate, microcrystalline cellulose (Avicel PH 102), povidone K30, sodium starch glycolate (explotab), talc purified.

ATENOLOL 50 KIARA: Opadry white Y-1-7000 (methocel E5 premium EP, titanium dioxide, polyethylene glycol 4000).
ATENOLOL 100 KIARA: Opadry orange OY-L-33047 (H.P.M.C 15 cps, lactose, titanium dioxide, polyethylene glycol 4000, sunset yellow lake, quinoline yellow lake).

What ATENOLOL KIARA looks like and contents of the pack
ATENOLOL 50 KIARA: White, round, biconvex, film-coated tablets.
ATENOLOL 100 KIARA: Orange, round, biconvex, film-coated tablets, scored on one side.

ATENOLOL 50 KIARA is supplied in blisters, amber glass containers, sealed aluminium bags or securitainers with 28, 30 or 100 tablets.
Blisters, amber glass containers or securitainers with 500 tablets.

ATENOLOL 100 KIARA is supplied in blisters, amber glass containers, sealed aluminium bags or securitainers with 28, 30 or 100 tablets.
Blisters, amber glass containers or securitainers with 500 tablets.

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

This leaflet was revised on
6 December 2022

Registration numbers
ATENOLOL 50 KIARA: X/5.2/388
ATENOLOL 100 KIARA: X/5.2/389

PASIËNTINLIGTINGSBLAADJIE
SKEDULERINGSTATUS: S3
ATENOLOL 50 KIARA (50 mg, filmbedekte tablette)
ATENOLOL 100 KIARA (100 mg, filmbedekte tablette)
Atenolol
Elke ATENOLOL 50 KIARA-filmbedekte tablet bevat suiker (laktose 63,5 mg).
Elke ATENOLOL 100 KIARA-filmbedekte tablet bevat suiker (laktose 127 mg).

Lees hierdie hele blaadjie sorgvuldig voordat u begin om ATENOLOL KIARA te neem
- Hou hierdie blaadjie. U mag nodig kry om dit weer te lees.
- Indien u enige verdere vrae het, vra u dokter of apteker.
- ATENOLOL 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.

1. Wat ATENOLOL KIARA is en waarvoor dit gebruik word
ATENOLOL KIARA bevat die aktiewe bestanddeel atenolol.
Atenolol behoort aan 'n groep medisyne wat adrenolitiese (simpatolitiese) middels genoem word.
ATENOLOL KIARA word vir die behandeling van hoë bloeddruk en angina pectoris (borskaspyn vanweë verminderde bloedvoorsiening aan die hart) gebruik.

2. Wat u nodig het om te weet voordat u ATENOLOL KIARA neem
Moenie ATENOLOL KIARA neem nie:
- Indien u hipersensitief (allergies) vir atenolol of vir enige van die ander bestanddele in ATENOLOL KIARA (gelys in afdeling 6) is.
- Indien u hartblok of 'n geskiedenis van hartversaking het.
- Indien u behandeling met verapamiel vir u hart ontvang.
- Indien u aan metaboliese asidose (waar die tempo van suurproduksie hoër as die tempo van suuruitskeiding is) ly, byvoorbeeld in diabetes mellitus.
- Indien u nie vir 'n verlengde periode geëet het nie.
- Indien u aan asma, brongitis, bradikardie (stadige hartklop), Raynaud se fenomeen (velsiekte) of enige ander chroniese respiratoriese siekte ly.

Waarskuwings en voorsorgmaatreëls
Tref spesiale sorg met ATENOLOL KIARA:
- Lig u dokter in indien u op behandeling met klonidien (vir hoë bloeddruk) is.
- Atenolol word in borsmelk uitgeskei. Lig u dokter in indien u borsvoed.
- Moenie skielik ophou om ATENOLOL KIARA te gebruik nie. Raadpleeg u dokter voordat u ophou om u tablette te neem.
- Lig u dokter van u behandeling met ATENOLOL KIARA in voor chirurgie wat narkose benodig.
- Die normale dosis moet in bejaarde pasiënte of in pasiënte met nierdisfunksie verminder word.

Ander medisyne en ATENOLOL KIARA
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem (dit sluit alle aanvullende of tradisionele geneesmiddels in).

Gepaardgaande gebruik van ATENOLOL KIARA met antidiabetiese medikasie, hartmedikasie of fenotiasiene mag lewensdreigend wees.

Die volgende medikasie mag die effekte van atenolol versterk:
- guanetidien en reserpien
- diasoksied
- klonidien
- diuretika (medikasie vir hoë bloeddruk, bv. furosemied).

Noradrenalien en adrenalien kan die uitwerking van ATENOLOL KIARA gevaarlik omkeer en gepaardgaande gebruik word nie aanbeveel nie.

ATENOLOL KIARA kan die effekte van lignokaïen, prokaïenamied, kinidien en fenitoïen versterk.

Lig u dokter in indien u allergeenimmunoterapie ontvang en voordat u veltoetsing met allergeniese ekstrakte laat doen.

Die gebruik van halotaan, chloroform, siklopropaan, enfluraan, isofluraan, metoksifluraan en trichlooretileen (narkosemiddels) met ATENOLOL KIARA kan tot 'n daling in harttempo en lae bloeddruk lei.

Teofillien en aminofillien (asmabehandeling) mag met die effektiwiteit van ATENOLOL KIARA inmeng.

ATENOLOL KIARA met voedsel, drankies en alkohol
U mag ATENOLOL KIARA met maaltye of op 'n leë maag neem.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u ATENOLOL KIARA neem.
Moenie ATENOLOL KIARA neem indien u swanger is of borsvoed nie.

Bestuur en die gebruik van masjinerie
ATENOLOL KIARA kan newe-effekte soos duiseligheid veroorsaak. Moenie 'n voertuig bestuur, masjinerie bedryf of enige iets anders wat u aandag vereis, doen voordat u nie weet hoe ATENOLOL KIARA u beïnvloed nie.

ATENOLOL KIARA bevat laktose
Indien u deur u dokter ingelig is dat u onverdraagsaam vir sekere suikers is, raadpleeg u dokter voordat u ATENOLOL KIARA neem.

3. Hoe om ATENOLOL KIARA te neem
Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Neem ATENOLOL KIARA altyd presies soos wat u dokter u opdrag gegee het. Kontak u dokter indien u onseker is.

Vir hipertensie: 100 mg daagliks as 'n enkele dosis.
Vir angina pectoris: 50 mg tot 100 mg daagliks toegedien as 'n enkele dosis of verdeelde dosisse.

Die normale dosis moet in bejaarde pasiënte of in pasiënte met nierdisfunksie verminder word.

Indien u die indruk het dat die effek van ATENOLOL KIARA te sterk of te swak is, gesels met u dokter of apteker.

Indien u meer ATENOLOL KIARA geneem het as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien u vergeet om ATENOLOL KIARA te neem
Moenie 'n dubbele dosis neem om vir vergete individuele dosisse op te maak nie. Gaan voort om die volgende tablet op die gewone tyd te neem. Indien u sukkel om te onthou wanneer om u medikasie te gebruik, vra u apteker vir 'n paar wenke.

4. Moontlike newe-effekte
ATENOLOL KIARA kan newe-effekte hê.
Nie alle newe-effekte wat vir ATENOLOL KIARA gemeld is, is in hierdie blaadjie ingesluit nie. Sou u algemene gesondheid agteruitgaan terwyl u ATENOLOL KIARA neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Die volgende newe-effekte is gerapporteer:
- Duiseligheid of lighoofdigheid wanneer opgestaan word, moeisame asemhaling.
- Swelling van die enkels, voete of onderbene, onreëlmatige hartklop, koue hande en voete en borskaspyn.
- Veluitslag, rooi en afskilferende (of korsvormende) vel.
- Rug- en gewrigspyn.
- Ongewone kneusing of bloeding.
- Verlaagde seksuele vermoë, sukkel om te slaap en ongewone moegheid.

Indien u enige newe-effekte opmerk wat nie in hierdie blaadjie genoem word nie, lig asseblief u dokter of apteker in.

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 Adverse Drug Reactions Reporting Form"** 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 veiligheid van ATENOLOL KIARA te voorsien.

5. Hoe om ATENOLOL KIARA te berg
Berg op 'n droë plek teen of onder 25 ºC en beskerm teen lig.
BEWAAR ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
Moenie die tablette na die vervaldatum wat op die stulpstrook en houer gedruk is, gebruik nie.
Besorg alle ongebruikte medisyne aan u apteker terug.
Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.
Bewaar die stulpstroke in die buitenste karton totdat dit vir gebruik benodig word.

6. Inhoud van die pakkie en ander inligting
Wat ATENOLOL KIARA bevat
- Die aktiewe bestanddeel is atenolol.

Elke ATENOLOL 50 KIARA-filmbedekte tablet bevat atenolol 50 mg.
Elke ATENOLOL 100 KIARA-filmbedekte tablet bevat atenolol 100 mg.
- Die ander bestanddele is:

Karnaoebawas, kolloïdale silikoondioksied (Aerosil), krospovidoon, etanol 96 %, isopropielalkohol, laktose, magnesiumstearaat, mikrokristallyne sellulose (Avicel PH 102), povidoon-K30, natriumstyselglikolaat (explotab), gesuiwerde talk.

ATENOLOL 50 KIARA: Opadry-wit Y-1-7000 (methocel E5 premium EP, titaandioksied, poliëtileenglikol 4000).
ATENOLOL 100 KIARA: Opadry-oranje OY-L-33047 (H.P.M.C 15 cps, laktose, titaandioksied, poliëtileenglikol 4000, sonsonderganggeellak, kinoliengeellak).

Waarna ATENOLOL KIARA lyk en inhoud van die pakkie
ATENOLOL 50 KIARA: Wit, ronde, bikonvekse, filmbedekte tablette.
ATENOLOL 100 KIARA: Oranje, ronde, bikonvekse, filmbedekte tablette, gekeep aan die een kant.

ATENOLOL 50 KIARA word voorsien in stulpstroke, amberkleurige glashouers, geseëlde aluminiumsakke of sekuriteitshouers met 28, 30 of 100 tablette.
Stulpstroke, amberkleurige glashouers of sekuriteitshouers met 500 tablette.

ATENOLOL 100 KIARA word voorsien in stulpstroke, amberkleurige glashouers, geseëlde aluminiumsakke of sekuriteitshouers met 28, 30 of 100 tablette.
Stulpstroke, amberkleurige glashouers of sekuriteitshouers met 500 tablette.

Houer van die Sertifikaat van Registrasie
Kiara Health (Pty) Ltd
72 Steel Road, Spartan
Kempton Park, 1619 South Africa

Hierdie blaadjie was laas hersien op
6 Desember 2022

Registrasienommers
ATENOLOL 50 KIARA: X/5.2/388
ATENOLOL 100 KIARA: X/5.2/389

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