

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.

What is in this leaflet

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

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: <http://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 °C 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

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