

## Patient Information Leaflet

### Scheduling status

**S3**

HEXA-BLOK 50 (film-coated tablets)

HEXA-BLOK 100 (film-coated tablets)

Atenolol

Each HEXA-BLOK 50 tablet contains sugar (2,88 mg lactose).

Each HEXA-BLOK 100 tablet contains sugar (4,32 mg lactose).

**Read all of this leaflet carefully before you start taking HEXA-BLOK 50 and HEXA BLOK**

#### **100**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **HEXA-BLOK** 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 HEXA-BLOK is and what it is used for
2. What you need to know before you take HEXA-BLOK
3. How to take HEXA-BLOK
4. Possible side effects
5. How to store HEXA-BLOK
6. Contents of the pack and other information

#### **1. What HEXA-BLOK is and what it is used for**



HEXA-BLOK is used in the management of high blood pressure and angina pectoris. Angina pectoris is a condition in which the cardiac muscles receive less oxygen than necessary. This generally occurs during exercise and the most common symptom is chest pain.

## 2. What you need to know before you take HEXA-BLOK

### ***Do not take HEXA-BLOK:***

- If you are hypersensitive (allergic) to atenolol or any of the other ingredients of HEXA-BLOK.
- If you have a condition called cardiogenic shock (a condition where the heart is unable to supply enough blood to the organs of the body).
- If you have a condition called sick sinus syndrome (a group of heart rhythm disorders).
- If you suffer from a condition called heart block (second or third degree).
- If you have an abnormally slow heartbeat (less than 45 beats per minute).
- If you have a condition called metabolic acidosis.
- If you suffer from a condition called pheochromocytoma (marked by high blood pressure, raised heart rate and headache), which is untreated.
- If you have uncontrolled heart failure.
- If you have low blood pressure.
- If you suffer from severe peripheral arterial circulatory disturbances (a circulatory problem in which narrowed arteries reduce blood flow to your limbs).

### **Warnings and precautions**

#### ***Take special care with HEXA-BLOK:***

- If you are using a medicine called clonidine and are being transferred to HEXA-BLOK. When stopping clonidine, you may experience extreme high blood pressure. Your doctor will monitor this transfer (see "Taking other medicines with HEXA-BLOK").
- If you are due to have an operation, you should inform your doctor or anaesthetist that you are taking HEXA-BLOK.
- If you suffer from asthma, bronchitis or other chronic lung diseases.

- Raynaud's phenomenon may develop (resulting in temporary discoloration of the skin and numbness of the fingers or toes).
- If you are elderly, or have kidney problems, as your dosage of HEXA-BLOK should be reduced. If you are elderly, your doctor will start your treatment with a lesser dose.
- Severe peripheral vascular disease (circulation disorder) and a condition called peripheral gangrene may be worsened.
- If you suffer from a type of chest pain (angina) called Prinzmetal's angina, HEXA-BLOK may increase the number and duration of attacks.
- If you suffer from circulatory problems or controlled heart failure.
- If you have first-degree heart block.
- HEXA-BLOK will reduce your heart rate, if your pulse drops to less than 50 – 55 beats per minute, your dosage should be reduced.
- If you have pheochromocytoma, which is being treated, your doctor will also prescribe a medicine called an alpha-blocker which should be taken with HEXA-BLOK.
- If you have diabetes. HEXA-BLOK may change how you respond to having low blood sugar. You may feel your heart beating faster.
- If you have thyrotoxicosis (a condition caused by an overactive thyroid gland).
- If you have a history of severe allergic reactions to any allergens (example insect stings), as HEXA-BLOK may cause a more severe reaction and you may be unresponsive to usual doses of medicine (adrenaline) used to treat your allergic reaction.
- If you have psoriasis, as HEXA-BLOK may aggravate your psoriasis (make it worse).
- If you use medicines for diabetes, phenothiazines (medicine used to treat mental disorders) and antidysrhythmic agents (medicines used to treat abnormal heart rate), you must tell your doctor.
- Do not stop taking your medicine without consulting your doctor first, your doctor will gradually reduce your dosage and will follow up, especially if you have heart problems.

### **Other medicines and HEXABLOK**

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

HEXA-BLOK may interact with the following medicines:

- Clonidine (for high blood pressure or migraine). If you are taking clonidine and HEXA-BLOK together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will give you careful instructions about how to do it.
- Verapamil, diltiazem and nifedipine (for high blood pressure and chest pain).
- Digoxin (heart medication). May cause a decrease in your heartbeat, which can be dangerous. Your doctor should monitor your pulse rate and response regularly.
- Adrenaline, also known as epinephrine.
- Oral blood sugar lowering medication or insulin (see “Take Special Care with HEXA-BLOK”).
- Ibuprofen or indomethacin (for pain and inflammation).
- Antiarrhythmic medicines (used to treat an irregular or rapid heartbeat), such as disopyramide, quinidine or amiodarone.
- Baclofen (muscle relaxer and an antispastic medicine).
- Anaesthetic medicines (medicines to sedate you during an operation) (see “Take Special Care with HEXA-BLOK”).

### **HEXA-BLOK with food or drink**

The tablets can be taken with or without food.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

The active ingredient of HEXA-BLOK (atenolol) is excreted into breast milk. Caution should be exercised if you are pregnant or breastfeeding.

### **Driving and using machinery**

It is unlikely for HEXA-BLOK to affect your ability to drive and use machinery, however, please make sure how HEXA-BLOK affects you before driving or using machinery. You must take into account that occasional dizziness or fatigue may occur.

### **Important information about some of the ingredients of HEXA-BLOK**

HEXA-BLOK contains lactose. Patients with rare hereditary conditions of galactose intolerance e.g., Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take HEXA-BLOK.

HEXA-BLOK contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

## **3. HOW TO TAKE HEXA-BLOK**

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

Always take HEXA-BLOK exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

### **For the treatment of angina:**

The usual dose is one HEXA-BLOK 50 tablet or one HEXA-BLOK 100 tablet daily as single or divided doses.

### **For the treatment of high blood pressure:**

The usual dose is one HEXA-BLOK 50 tablet once daily. If your doctor decides that your response is not adequate, your dose may be increased to one HEXA-BLOK 100 tablet once daily.

The tablets should be taken at about the same time each day.

Your doctor may prescribe additional medication with HEXA-BLOK such as water tablets (diuretics).

Your doctor will tell you how long your treatment with HEXA-BLOK will last. If you have the impression that the effect of HEXA-BLOK is too strong or too weak, tell your doctor or pharmacist.

**If you take more HEXA-BLOK than you should:**

In the event of overdosage, consult your doctor or pharmacist, if neither is available, contact the nearest hospital or poison control centre.

**If you forget to take of HEXA-BLOK:**

If you forget to take a dose of the HEXA-BLOK, take it as soon as you remember, unless it is time for your next dose.

Do not take a double dose to make up for forgotten individual doses.

#### **4. POSSIBLE SIDE EFFECTS**

HEXA-BLOK can have side effects.

Not all side effects reported for HEXA-BLOK are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

**If any of the following happen, stop taking HEXA-BLOK and contact your doctor immediately or go to the casualty department at your nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing.
- A rash or itching.
- Fainting.
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to HEXA-BLOK. You may need urgent medical attention or hospitalisation.

Side effects that may occur frequently include:

- Unusual tiredness or weakness.
- Nausea or vomiting.
- An upset stomach or stomach pain.
- Cold hands and feet.
- Low blood pressure (dizziness, tiredness).
- Slow heartbeat.

Less frequent side effects that may occur include the following:

- Depressive mood, confusion, psychoses and hallucinations, mood changes, nightmares and sleep disturbances.
- Dizziness, headache and tingling of your hands.
- Hearing loss.
- Skin rash.
- Low blood sugar levels.
- Fluid retention and mass gain.
- Hair loss.
- Dry eyes and vision disturbances.
- Being unable to get an erection (impotence).
- Muscle weakness.
- Difficulty breathing if you are suffering from asthma or a lung disease.
- Reduced number of platelets in your blood (this may make you bruise more easily).
- Purplish marks on your skin.
- Heart failure deterioration, worsening of heart block.

- Raynaud's phenomenon (temporary discoloration of the skin and numbness of the fingers or toes).
- Low blood pressure (dizziness, tiredness).
- Dry mouth, constipation.
- Yellowing of your skin or the whites of your eyes (jaundice).
- Changes to some of the cells or other parts of your blood. Your doctor may do blood tests to check if HEXA-BLOK has had any effect on your blood.

Frequency unknown side effects that may occur include the following:

- Constipation
- Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints).

### **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 HEXA-BLOK.

Suspected side effects can also be reported directly to the HCR via [Patientsafety.sacg@novartis.com](mailto:Patientsafety.sacg@novartis.com).

### **5. How to store HEXA-BLOK**

Store in well-closed containers at or below 25 °C.

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

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 HEXA-BLOK contains**

### ***HEXA-BLOK 50:***

Active ingredient: Each tablet contains 50 mg Atenolol.

The other ingredients are:

Core: heavy magnesium carbonate, hydroxypropylcellulose, magnesium stearate, maize starch, sodium dodecyl sulphate and sodium starch glycolate.

Film-coating: Opadry white (consisting of lactose monohydrate, methylhydroxypropylcellulose, polyethylene glycol 4000 and titanium dioxide).

Contains sugar (2,88 mg lactose).

### ***HEXA BLOK 100:***

Active ingredient: Each tablet contains 100 mg Atenolol.

The other ingredients are:

Core: heavy magnesium carbonate, hydroxypropylcellulose, magnesium stearate, maize starch, sodium dodecyl sulphate and sodium starch glycolate.

Film-coating: Opadry white (consisting of lactose monohydrate, methylhydroxypropylcellulose, polyethylene glycol 4000 and titanium dioxide).

Contains sugar (4,32 mg lactose).

## **What HEXA-BLOK looks like and contents of the pack**

HEXA-BLOK 50 is a round, white, film-coated tablet, scored on one side and embossed "50" on the other side.

HEXA BLOK 100 is a round, white, film-coated tablet, scored on one side and embossed "100" on the other side.

### **HEXA-BLOK is packed in:**

HEXA-BLOK 50: PVC /Aluminium Blister packs, containing 30 tablets.

HEXA BLOK 100: PVC /Aluminium Blister packs, containing 30 tablets.

**Holder of Certificate of Registration**

Sandoz SA (Pty) Ltd<sup>1</sup>

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Magwa Crescent West

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Jukskei View

2090

**This leaflet was last revised in**

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**Registration numbers**

HEXA-BLOK 50: 27/5.2/0468

HEXA BLOK 100: 27/5.2/0469

**Access to the corresponding Professional Information**

Not applicable.

<sup>1</sup>Company Reg. No.: 1990/001979/07