**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S3

**BIGSENS XR extended release tablets**

**BIGSENS XR 750 extended release tablets**

**BIGSENS XR 1 000 extended release tablets**

**Metformin hydrochloride**

**Sugar free.**

**Read all of this leaflet carefully before you start taking BIGSENS XR**

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


## 1. What BIGSENS XR is and what it is used for

Each extended release BIGSENS XR tablet contains 500 mg metformin hydrochloride.

Each extended release BIGSENS XR 750 tablet contains 750 mg metformin hydrochloride.

Each extended release BIGSENS XR 1 000 tablet contains 1 000 mg metformin hydrochloride.

BIGSENS XR is used to treat high blood sugar levels when diet and exercise alone do not result in adequate control of blood sugar levels.

BIGSENS XR can be taken on its own, or with other oral antidiabetic medicines or insulin, to lower your blood glucose level, if it is too high.

## 2. What you need to know before you take BIGSENS XR

**Do not take BIGSENS XR:**

- If you are hypersensitive (allergic) to metformin hydrochloride or any of the other ingredients of BIGSENS XR (see section 6).
- If you have previously had a serious problem with your diabetes, called diabetic ketoacidosis (when you have this you feel thirsty, sick, weak, breathless and lose weight quickly).
- If you have kidney or liver problems.
- If you are dehydrated or have a severe infection.
- If you recently had severe heart or breathing problems.
- If you recently had an X-ray where a dye was injected.
- If you drink a lot of alcohol.
- If you are pregnant or breastfeeding.

**Warnings and precautions**

**Take special care with BIGSENS XR:**

- If you regularly skip meals, drink too much alcohol or have liver problems. Taking BIGSENS XR under these conditions can lead to a condition called lactic acidosis. This is a serious condition caused by a build-up of lactic acid in the blood. You should stop taking BIGSENS XR and call your doctor immediately if you have signs of lactic acidosis.

  **Lactic acidosis is a medical emergency and must be treated in a hospital.**

  Signs of lactic acidosis are:

  - feeling very weak, tired or uncomfortable
  - unusual muscle pain
  - difficulty breathing

    - unusual or unexpected stomach discomfort
    - feeling cold
    - feeling dizzy or light-headed
    - sudden changes in heartbeat (slow or irregular).
- If your doctor advised you to stop smoking, change your diet or exercise regularly. It is important that you follow this advice.
- If you start a new exercise program. Check with your doctor first, as this will have an effect on your blood sugar levels and you may need to check your blood or urine levels more regularly.
- If you have an illness that causes severe vomiting, diarrhoea or fever, or if you drink much less liquids than normally. These can lead to severe dehydration (loss of fluid in your body). You may need to stop taking BIGSENS XR.
- If you get unusually thirsty, pass urine more frequently and feel very tired, then let your doctor know. Your dose of BIGSENS XR may need to be adjusted.
- If you need to have an examination, such as an X-ray scan involving the injection of contrast medium containing iodine into your bloodstream (see Other medicines and BIGSENS XR).
- If you are due to have an operation, you should stop taking BIGSENS XR 48 hours (2 days) before your surgery with anaesthesia. You should only take BIGSENS XR 48 hours (2 days) after your operation.
- If you have kidney problems.
- If you have diabetes, you should have your blood or urine sugar levels tested regularly. Your doctor will specify how often your kidney function will be checked depending on your condition.
- If you have heart problems but your condition is under control, your doctor will monitor your heart and kidney function regularly.

**Other medicines and BIGSENS XR:**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please avoid taking medicines containing alcohol (a lot of cough mixtures contain alcohol).

Tell your doctor if you are planning to have surgery or an X-ray procedure.

Tell your doctor or pharmacist if you are currently using:

- nonsteroidal anti-inflammatory drugs (NSAIDs), selective cyclo-oxygenase (COX) II inhibitors (used to treat pain and inflammation),
- glucocorticoids (medicine to treat diseases caused by an overactive immune system),
- ACE inhibitors, angiotensin II receptor antagonists, diuretics (a group of medicines used to treat high blood pressure),
- verapamil (used to treat high blood pressure),
- rifampicin (used to treat tuberculosis [TB]),
- cimetidine (a medicine that reduces stomach acid),
- dolutegravir (used in the treatment of HIV [human immunodeficiency virus] and AIDS [acquired immune deficiency syndrome]),
- ranolazine (used to treat angina [chest pain when your heart does not get enough oxygen]),
- trimethoprim (used to treat bacterial infections),
- vandetanib (used to treat thyroid cancer),
- isavuconazole (used to treat fungal infections),
- crizotinib (used to treat lung cancer),
- olaparib (used to treat ovarian cancer),
- anticoagulants (medicines that prevent your blood from clotting),
- sulphonylureas (antidiabetic medication),
- vitamin $B_{12}$.

**BIGSENS XR with food and drink**

You should take BIGSENS XR with meals, swallowed whole, not chewed, and with a glass of plain water. This will help to reduce stomach or bowel side effects that may occur during the first few weeks of treatment.

When you start taking BIGSENS XR it is usually taken with the evening meal.

Drinking alcohol with BIGSENS XR is not recommended. It lowers blood sugar and may increase your risk of lactic acidosis while taking BIGSENS XR (see Take special care with BIGSENS XR).

**Pregnancy and breastfeeding**

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 health care provider for advice before taking BIGSENS XR.

DO NOT take BIGSENS XR if you are pregnant.

DO NOT take BIGSENS XR if you are breastfeeding as BIGSENS XR is excreted in breast milk in small quantities.

**Driving and using machines**

BIGSENS XR taken with other medicines to lower blood sugar, may impair your ability to drive a vehicle and use machinery. Do not drive a vehicle or operate any machinery or tools until you know how BIGSENS XR affects you.

## 3. How to take BIGSENS XR

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

**Always take BIGSENS XR exactly as your doctor has instructed you. You should check with your** doctor or pharmacist if you are unsure.

**BIGSENS XR:**

The usual starting dose is one tablet (500 mg) daily with your evening meal. Your doctor may adjust your dose after 10 to 15 days. The maximum recommended dosage is usually not more than 4 tablets daily.

**BIGSENS XR 750:**

The usual starting dose is one tablet (750 mg) daily with your evening meal.

Your doctor may adjust your dose after 10 to 15 days. The recommended dosage is 2 tablets daily.

**BIGSENS XR 1 000:**

The usual starting dose is one tablet (1 000 mg) daily with the evening meal at a maximum

recommended dose of 2 tablets per day.
BIGSENS XR 1 000 is intended as maintenance therapy for patients currently treated with either 1 000 mg or 2 000 mg of metformin hydrochloride.

Swallow the tablets whole, do not chew or crush them.
Your doctor may slowly increase your dosage until the levels of your blood sugar are controlled.
Your doctor may want you to take other medicines along with BIGSENS XR to help control your blood sugar levels better.
If you have the impression that the effect of BIGSENS XR is too strong or too weak, talk to your doctor or pharmacist.

**If you take more BIGSENS XR than you should**

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take this leaflet and the rest of the remaining BIGSENS XR with you so the doctor will know what you have taken.

**If you forget to take BIGSENS XR**

If you have missed your dose by only a few hours, take the missed dose as soon as you remember with food. If it is almost time for your next dose, skip the missed dose and take BIGSENS XR at the next regularly scheduled time. **Do not** take a double dose to make up for the forgotten individual doses.

## 4. Possible side effects

BIGSENS XR can have side effects.
Not all side effects reported for BIGSENS XR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIGSENS XR, please consult your health care provider for advice.

**If any of the following happens, stop taking BIGSENS XR and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Difficulty breathing, dizziness (severe hypersensitivity).

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

**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

*Less frequent:*

- Lactic acidosis (characterised by intense stomach pain and low body temperature, feeling dizzy).
- Hypoglycaemia (very low blood sugar levels).

These are all serious side effects. You may need urgent medical attention.

**Tell your doctor as soon as possible if you notice any of the following:**

*Frequent:*

- Unpleasant metallic taste when starting on BIGSENS XR therapy.
- Lack of appetite, abdominal pain, feeling sick or being sick, diarrhoea.

*Less frequent:*

- Anaemia (characterised by a low amount of red blood cells when blood tests are done).

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, pharmacist or nurse. You can also report side effects via the 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 BIGSENS XR.

## 5. How to store BIGSENS XR

- BIGSENS XR: Store at or below 25 °C.
- BIGSENS XR 750: Store at or below 30 °C.
- BIGSENS XR 1 000: Store at or below 30 °C.
- Keep the blister strips in the outer carton until required for use.
- Protect from light and moisture.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- 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 BIGSENS XR contains:**

The active substance is metformin hydrochloride.

The other ingredients are glyceryl behenate, hypromellose, microcrystalline cellulose and povidone.

**What BIGSENS XR looks like and contents of the pack:**

BIGSENS XR: White to off-white, capsule shaped, uncoated tablets, debossed with ‘63’ on one side and ‘Z’ on the other side.

BIGSENS XR 750: White to off-white, capsule shaped, biconvex tablets, plain on both sides.

BIGSENS XR 1 000: White to off-white, capsule shaped, bevelled biconvex tablets, plain on both sides.

Clear, transparent PVC/PVDC/silver aluminium blister strips, containing 10 tablets each. Blister strips are packed in an outer cardboard box.

BIGSENS XR: Pack sizes: 90, 120 or 360 tablets.

BIGSENS XR 750: Pack sizes: 60 or 90 tablets.

BIGSENS XR 1 000:  Pack sizes: 60 or 90 tablets.

**Holder of Certificate of Registration**

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BIGSENS XR: 51/21.2/0683

BIGSENS XR 750: 55/21.2/0672

BIGSENS XR 1 000: 55/21.2/0673

**Dates of registration**

BIGSENS XR: 1 August 2019

BIGSENS XR 750: 18 July 2023

BIGSENS XR 1 000: 18 July 2023