PATIENT INFORMATION LEAFLET

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine 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.

SCHEDULING STATUS

S 3

PROPRIETARY NAME

Bigsens 500 film coated tablets

Bigsens 850 film coated tablets

Bigsens 1000 film coated tablets

What information will you find in this leaflet:

1. What does **BIGSENS** tablets contain?
2. What are **BIGSENS** tablets used for?
3. Before you take your **BIGSENS** tablets.
4. How to take your **BIGSENS** tablets.
5. Possible side effects of **BIGSENS** tablets
6. How to store your **BIGSENS** tablets.
7. How are **BIGSENS** tablets packed?
8. How do **BIGSENS** tablets look?

1. What is in BIGSENS tablets?

BIGSENS tablets are available in three strengths:

- **BIGSENS 500 film coated** tablets contain 500 mg metformin hydrochloride, which is the active ingredient, this is an immediate release tablet
- **BIGSENS 850 film coated** tablets contain 850 mg metformin hydrochloride, which is the active ingredient, this is an immediate release tablet
- **BIGSENS 1000 film coated** tablets contain 1000 mg metformin hydrochloride, which is the active ingredient, this is an immediate release tablet

BIGSENS 500, 850 and BIGSENS 1000 film coated tablets also contain the following inactive ingredients: hydroxypropyl methylcellulose, microcrystalline cellulose, magnesium stearate, povidone, and opadry clear 03F59016IH as the colourant

2. What are BIGSENS tablets used for?

BIGSENS is indicated to treat patients with type 2 diabetes to control high blood sugar levels that cannot be controlled by diet management, exercise, or weight reduction, or when insulin therapy cannot be used.

BIGSENS tablets can be prescribed alone or in combination with other medicines.

3. Before you take BIGSENS tablets

Do not take this medicine if you:

- Are hypersensitive to any of the compounds.
- Are pregnant.
- Have severe infections
- Have kidney, liver, pancreas or lung problems
- Have heart failure
- Take excessive quantities of alcohol.
- Just had an operation

Metformin can possibly cause ketoacidosis in children after exercise

Talk to your doctor before taking BIGSENS tablets:

- If you develop a serious illness or requires surgery while or before you start taking ***Bigsens*** *tablets*
- The use of metformin hydrochloride is not advised in diabetics in children
- A reduced absorption of vitamin B_{12} can occur during long term therapy with metformin tablets and your doctor could decide to give you a vitamin B_{12} injection

Important: ***BIGSENS*** *tablets should and cannot be a substitute for diet or weight control*.

***Can I take BIGSENS tablets with other medicines*?**

If you are taking other medicines on a regular basis including complementary medicines together with BIGSENS tablets, it may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice, if you are taking any of the following medication:

- sulphonylureas
- vitamin B12 or folic acid supplements
- anticoagulants (medicine that prevent your blood from clogging)
- cimetidine (medicine that reduce stomach acid)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding do not take this medicine until you have talked to your doctor. Consult your doctor immediately if you become pregnant while taking this medicine.

Driving and using machines

If you suffer from dizziness, headaches, tiredness or nausea make sure that you are well enough to drive or operate machinery, as your ability to react may be impaired.

4. How to take your BIGSENS tablets

Follow your doctor's advice. The tablets should be swallowed whole with a glass of water and should be taken the same time each day. 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.

It is important that Metformin hydrochloride tablets be taken in divided doses with meals to reduce nausea and diarrhoea.

Adults: Initially, one 500 mg tablet three times a day, with or after food.

After 10 to 15 days the dose should be adjusted, or increased to 850 mg or 1000 mg twice daily. Your doctor may decide to reduce or increase the dosage once your diabetes is under control.

Children: BIGSENS is not recommended for use in type 1 diabetes mellitus.

What if you miss a dose?

If you forget to take a dose, take it as soon as you remember. Then go on as before. **Do not take two doses at the same time.**

What if you have taken too many tablets?

In the event of an overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre **immediately**. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

5. Possible side effects

Like all medicines, **BIGSENS** tablets can cause side effects in some patients.

Gastrointestinal disorders:

The most frequent side-effects that occur are gastrointestinal side-effects such as flatulence, nausea, vomiting and diarrhoea;

Nausea and diarrhoea occur less frequent when small doses are used when you first start taking the medicine. If diarrhoea occurs after several months of metformin therapy you should immediately tell your doctor.

Metabolism and nutrition disorders:

Anorexia and loss in body mass occur most frequently.

Hypoglycemia (anxiousness, cold sweats, concentration difficulties, confusion, cool pale skin, drowsiness, excessive hunger, headache, nausea, nervousness, rapid pulse, shakiness, unusual tiredness or weakness, vision changes) and lactic acidosis (diarrhoea, fast shallow breathing, muscle pain or cramping, sleepiness, unusual tiredness or weakness) occur less frequently.

Skin and subcutaneous tissue disorders:

Itching and rash have also been reported.

General disorders:

Metallic taste, tiredness, weakness and headache have been reported.

Not all side-effects reported for BIGSENS tablets are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. Storing your BIGSENS tablets

Store at or below 25 °C.

Store in the original package to protect from light and moisture.

Do not store your medicine in the bathroom.

Do not use **BIGSENS** tablets after the expiry date printed on the label or blister.

Return the expired medicine to your pharmacist for safe disposal.

KEEP BIGSENS TABLETS OUT OF THE REACH AND SIGHT OF CHILDREN.

7. How do BIGSENS tablets look?

Bigsens 500 film coated tablet is a white to off-white round shaped film-coated tablet with the logo of '70' on one side and 'Z' on the other side.

Bigsens 850 film coated tablets is a white to off-white oval shaped film-coated tablet with the logo of '69' on one side and 'Z' on the other side.

BIGSENS 1000 film coated tablet is a white to off-white oval shaped film-coated tablet debossed with the logo of '71' on one side and 'Z' on the other side

8. How are BIGSENS tablets packed?

Bigsens 500 film coated tablets are packed as 100, 500 and 1000 tablets in white plastics containers with white plastic child resistant caps.

Bigsens 850 film coated tablets are packed as 100, 500 and 1000 tablets in white plastics containers with white plastic child resistant caps.

BIGSENS 1000 film coated tablets are packed as 60, 100, 500 and 1000 tablets in white HDPE containers with white PP child resistant caps

REGISTRATION NUMBERS:

BIGSENS 500 film coated tablets: 39/21.2/0638

BIGSENS 850 film coated tablets: 39/21.2/0639

BIGSENS 1000 film coated tablets: 41/21.2/0193

NAME AND ADDRESS OF REGISTRATION HOLDER:

Zydus Healthcare S.A. (Pty) Ltd.

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

To be allocated by Council