PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

GLIZEB 25 film-coated tablets

GLIZEB 50 film-coated tablets

GLIZEB 100 film-coated tablets

Sitagliptin

Sugar free.

Read all of this leaflet carefully before you start taking GLIZEB

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

1. What GLIZEB is and what it is used for

GLIZEB contains the active substance sitagliptin which is a member of a class of medicines called dipeptidyl peptidase-4 (DPP-4) inhibitors that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

Your doctor has prescribed **GLIZEB** to help lower your blood sugar, which is too high because of your type 2 diabetes. **GLIZEB** helps to increase the levels of insulin produced in your body after a meal and decreases the amount of sugar made by your body.
GLIZEB can be used alone or in combination with certain other medicines that lower blood sugar, which you may already be taking for your diabetes, together with a diet and exercise plan.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in your blood. This can lead to serious medical problems.

2. What you need to know before you take GLIZEB

Do not take GLIZEB

- if you are hypersensitive (allergic) to sitagliptin or to any of the other ingredients of **GLIZEB** listed in section 6 of this leaflet;
- if you previously had an allergic reaction to any other medicine which is also a member of the class of medicines called dipeptidyl peptidase-4 (DPP-4) inhibitors;
- if you suffer from severe liver disease;

Warnings and precautions

Take special care with:

- type 1 diabetes;
- a disease of the pancreas (such as pancreatitis);
- any kidney problems or a history of kidney problems;

Tell your doctor if you experience any of the following while taking **GLIZEB**:

- an allergic reaction (see section 4);
- inflammation of your pancreas (pancreatitis) (causing pain of your upper stomach area that radiates to your back, fever, nausea, vomiting and tenderness of your stomach area). Cases of pancreatitis have been reported in patients taking **GLIZEB**;
- if you encounter blistering of the skin, it may be a sign of a condition called bullous pemphigoid.

GLIZEB is unlikely to cause low blood sugar because it does not work when your blood sugar is low. However, when **GLIZEB** is used in combination with a sulphonylurea medicine or with insulin, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your sulphonylurea or insulin medicine.

Children and adolescents

GLIZEB is not recommended for use in children and adolescents under 18 years of age.

Other medicines and GLIZEB

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

Tell your doctor if you are taking digoxin (used to treat an irregular heart beat or other heart problems). Your doctor may have to check the level of digoxin in your blood if you are taking **GLIZEB**.

GLIZEB with food and drink

See section 3.

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 healthcare provider for advice before taking **GLIZEB**.

If you are pregnant or breastfeeding your baby, you should not use **GLIZEB**.

Driving and using machines

GLIZEB has no or negligible influence on the ability to drive and use machines. However, **GLIZEB** can cause side effects, such as dizziness or drowsiness. You should not drive a vehicle, or operate machinery until you know how **GLIZEB** affects you.

Taking **GLIZEB** in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia (low blood sugar), which may affect your ability to drive and use machines or work without safe foothold.

3. How to take GLIZEB

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

Always take or give **GLIZEB** exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 100 mg once daily when used with other medicines that are used to treat diabetes.

Your doctor may adjust your dose if you have kidney problems.

Your doctor will tell you how long your treatment with **GLIZEB** will last. Do not stop treatment with **GLIZEB** unless your doctor tells you to.

GLIZEB can be taken with or without food.

If you have the impression that the effect of **GLIZEB** is too strong or too weak, tell your doctor or pharmacist.

If you take more GLIZEB than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You or a child in your care may may require medical attention. Take the medicine pack with you.

If you forget to take GLIZEB

If you forget a dose, take it as soon as you remember. However if it is nearly time for the next dose, skip the missed dose.Then continue with your normal schedule. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

GLIZEB can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **GLIZEB**. 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:

- severe and persistent pain in the abdomen (stomach area) which might reach through to your back with or without nausea and vomiting, as these could be signs of an inflamed pancreas (pancreatitis);
- severe blistering skin rash, known as Stevens-Johnson syndrome or bullous pemphigoid;
- reduced number of platelets in your blood (which can affect clotting and cause unexplained bleeding or bruising);
- difficulty breathing due to scarring of your lung tissues;
- kidney problems (shortness of breath, more or less urine than is normal for you, confusion, drowiness).

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache.

Less frequent side effects:

- dizziness;
- constipation.

The following side effects may occur, but the frequency is unknown:

- upper respiratory tract infections, stuffy or runny nose and sore throat;
- vomiting (being sick);
- joint pain, muscle pain, back pain or joint degeneration.

The following side effects may occur when **GLIZEB** is used with other diabetic medicines:

*Side effects which occur frequently when using **GLIZEB** with sulphonylurea and metformin:*

- low blood sugar (dizziness, light-headedness);
- constipation.

*Side effects which occur frequently when using **GLIZEB** with insulin:*

- flu.

*Side effects which occur less frequently when using **GLIZEB** with insulin (with or without metformin):*

- dry mouth.

*Side effects which occur frequently when using **GLIZEB** with metformin:*

- nausea (feeling sick);
- vomiting (being sick);
- flatulence (excessive wind).

*Side effects which occur less-frequently when using **GLIZEB** with metformin:*

- drowsiness;
- diarrhoea.

*Side effects which occur frequently when using **GLIZEB** with pioglitazone:*

- flatulence (excessive wind);
- swelling of your hands, feet, arms or legs due to water retention.

*Side effects which occur frequently when using **GLIZEB** with pioglitazone and metformin:*

- swelling of your hands, feet, arms or legs due to water retention.

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. This includes any possible side effects not listed in this leaflet. 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 **GLIZEB**.

5. How to store GLIZEB

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or container.
- 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 GLIZEB contains

The active substance in **GLIZEB** is sitagliptin.

GLIZEB 25: Each film-coated tablet 25 mg sitagliptin.

GLIZEB 50: Each film-coated tablet 50 mg sitagliptin.

GLIZEB 100: Each film-coated tablet 100 mg sitagliptin.

The other ingredients are:

Tablet core:

Colloidal silicon dioxide (E551)

Croscarmellose sodium (E468)

Dibasic calcium phosphate (E341)

Magnesium stearate (E572)

Malic acid (E296)

Microcrystalline cellulose (E460)

Povidone (E1201)

Film-coating:

GLIZEB 25:

Opadry white (containing macrogol (E1521), polyvinyl alcohol (E1203), talcum (E553b), titanium dioxide (E171))

GLIZEB 50:

Opadry yellow (containing ferrosoferric oxide (E172), iron oxide yellow (E172), macrogol (E1521), polyvinyl alcohol (E1203), talcum (E553b), titanium dioxide (E171))

GLIZEB 100:

Opadry beige (containing FD&C yellow (E110), iron oxide yellow (E172), macrogol (E1521), polyvinyl alcohol (E1203), talcum (E553b), titanium dioxide (E171))

What GLIZEB looks like and contents of the pack

GLIZEB 25: White to off-white, round, biconvex, film-coated tablets, debossed with ‘12’ on one side and ‘40’ on the other side.

GLIZEB 50: Pale yellow coloured, round, biconvex, film-coated tablets, debossed with ‘12’ on one side and ‘41’ on the other side.

GLIZEB 100: Beige coloured, round, biconvex, film-coated tablets, debossed with ‘12’ on one side and ‘42’ on the other side.

Aluminium/aluminium blister strip containing 10 film-coated tablets packed into an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

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0157

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