PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

SALUMET 50/500 film-coated tablets

SALUMET 50/1 000 film-coated tablets

Sitagliptin & metformin hydrochloride

Sugar free.

Read all of this leaflet carefully before you start taking SALUMET:

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

1. What SALUMET is and what it is used for

SALUMET contains two different medicines, namely sitagliptin and metformin, which work together to control blood sugar levels in adults with type 2 diabetes mellitus:

- Sitagliptin is a member of a class of medicines called dipeptidyl peptidase-4 (DPP-4) inhibitors.
- Metformin belongs to a class of medicines called biguanides.

Along with diet and exercise, SALUMET helps lower your blood sugar. SALUMET can be used alone or with a sulphonylurea (an alternative type of medicine used to treat diabetes).

2. What you need to know before you take SALUMET

Do not take SALUMET:

- If you are hypersensitive (allergic) to sitagliptin or metformin or to any of the other ingredients of SALUMET listed in section 6 of this leaflet.
- If you have previously had an allergic reaction to SALUMET or any other gliptins (used to treat type 2 diabetes mellitus).
- If you have kidney problems.
- If you are dehydrated, in shock or have a severe infection.
- If you are going to have an X-ray where you will be injected with a dye. You will need to stop taking SALUMET and wait for at least 48 hours after this procedure, and for clearance from your doctor, before you start taking SALUMET again.
- If you have acute or chronic metabolic acidosis (fast breathing, mental confusion, vomiting (being sick)), including diabetic ketoacidosis. Ketoacidosis is a condition in which substances called “ketone bodies” accumulate in your blood, which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- If you have uncontrolled diabetes, with symptoms such as severe hyperglycaemia (high blood glucose), nausea, vomiting or diarrhoea.
- If you have recently had a heart attack or have severe circulatory problems, such as “shock” or breathing difficulties.
- If you have liver problems.
- If you drink alcohol a lot (all the time or you binge-drink from time to time).
- If you are breastfeeding.

Warnings and precautions:

Talk to your doctor before taking SALUMET if you have any of the following:

- Type 1 diabetes. You should not take SALUMET if you have type 1 diabetes.
- A disease of the pancreas (such as pancreatitis).
- Any kidney problems or a history of kidney problems. Your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

Stop taking SALUMET immediately if you:

- Experience an allergic reaction (see section 4).
- Experience inflammation of your pancreas (pancreatitis) (causing pain in your upper stomach area that radiates to your back, fever, nausea, vomiting and tenderness of your stomach area). Contact your doctor immediately.
- Experience some of the symptoms of lactic acidosis. The risk of developing lactic acidosis is increased with uncontrolled diabetes, if your kidneys are not working properly, during serious infections, prolonged fasting or alcohol intake, dehydration (also see below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease). Symptoms of lactic acidosis include: vomiting, pain in your stomach area, muscle cramps, a general feeling of being unwell with severe tiredness, difficulty in breathing, reduced body temperature and heartbeat. Stop taking SALUMET and speak to your doctor immediately, as this condition may lead to a coma. Lactic acidosis is a medical emergency and must be treated in a hospital.
- Encounter blistering of the skin; it may be a sign of a condition called bullous pemphigoid.
- Experience any condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat, or if you drink less fluid than normal. Talk to your doctor for further instructions, as he may want you to stop taking SALUMET for a short time.

Take special care with SALUMET if you:

- Are taking other medicines that lowers your blood sugar levels together with SALUMET (e.g. sulphonylureas, insulin or other diabetes medicine). You may experience low blood sugar levels

(hypoglycaemia). Your doctor may want you to reduce the dose of your sulphonylurea or insulin.

- Have heart or liver problems, inform your doctor that you are taking SALUMET.
- Are an elderly or malnourished person.
- Are going to have a major operation where your food and fluid intake will be restricted prior to the operation. You should stop taking SALUMET before the operation and for some time after the operation. Your doctor will decide when you must stop taking SALUMET and when you can start taking SALUMET again.
- Have a tendency to develop subnormal levels of vitamin B_{12}. SALUMET can interfere with vitamin B_{12} absorption and cause decreased serum vitamin B_{12} levels in your body.

Children and adolescents:

Do not give SALUMET to children and adolescents below the age of 18 years, as it is not known whether SALUMET is safe and effective when used in children and adolescents under the age of 18 years.

Other medicines and SALUMET:

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:

- Medicines (taken by mouth, inhalation, or injection) used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids).
- Medicines which increase urine production (diuretics).
- Medicines used to treat pain and inflammation (any nonsteroidal anti-inflammatory medicines or COX-2 inhibitors, such as ibuprofen and celecoxib).
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- Specific medicines for the treatment of bronchial asthma (β-sympathomimetics).
- Iodinated contrast medicines or alcohol-containing medicines.

- Certain medicines used to treat stomach problems such as cimetidine.
- Ranolazine, a medicine used to treat angina.
- Dolutegravir, a medicine used to treat HIV infection.
- Vandetanib, a medicine used to treat a specific type of thyroid cancer (medullary thyroid cancer).
- Digoxin, a medicine used to treat an irregular heartbeat or other heart problems). Your doctor may have to check the level of digoxin in your blood if you are taking SALUMET.

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of an X-ray or scan, you must stop taking SALUMET before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with SALUMET.

SALUMET with food and drink:

Avoid excessive alcohol intake while taking SALUMET since this may increase the risk of lactic acidosis (see section “Warnings and precautions”).

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 SALUMET.

You should not take SALUMET if your are pregnant.

Do not breastfeed your baby if you are taking SALUMET.

Driving and using machines:

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

Taking SALUMET 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 SALUMET

Do not share medicines prescribed for you with any other person.
Always take SALUMET 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 one tablet taken twice daily by mouth. The tablets should be taken with meals to lower your chance of an upset stomach.

Your doctor may need to increase your dose to control your blood sugar levels.

You should continue the diet recommended by your doctor during treatment with SALUMET and take care that your carbohydrate intake is equally distributed throughout the day.

SALUMET alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When SALUMET is used with a sulphonylurea medicine or with insulin, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

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

If you take more SALUMET than you should:
In the event of overdosage, consult your doctor or pharmacist without delay. Go to the hospital if you have symptoms of lactic acidosis such as feeling cold or uncomfortable, severe nausea or vomiting, stomach ache, muscular cramps, or rapid breathing (see section “Warnings and precautions”). You may require medical attention. Take this leaflet and the remaining SALUMET

with you so the doctor will know what you have taken.

If you forget to take SALUMET:

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 and then continue with your normal schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking SALUMET:

Continue to take SALUMET for as long as your doctor prescribes it.

You should not stop taking SALUMET without talking to your doctor first. Your blood sugar levels may increase when you stop taking SALUMET.

4. Possible side effects

SALUMET can have side effects.

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

If any of the following happens, stop taking SALUMET 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 SALUMET. 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).
- Lactic acidosis (vomiting, pain in your stomach area, muscle cramps, a general feeling of being unwell with severe tiredness, difficulty in breathing, reduced body temperature and heartbeat) (see section “Warnings and precautions”).
- Severe, painful blistering skin or peeling skin rash, known as Stevens-Johnson syndrome or bullous pemphigoid.
- Difficulty breathing, shortness of breath, fast breathing, dry cough or fatigue (due to scarring of your lung tissues).
- Kidney problems (producing more or less urine than is normal for you, confusion, drowiness).
- Low blood sugar levels (sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, fast pounding heartbeat).
- Yellowing of your skin and eyes, also called jaundice or hepatitis.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea (feeling sick), vomiting (being sick), flatulence (wind), diarrhoea, loss of appetite, metallic taste in your mouth.
- Nasopharyngitis (sore throat, runny or blocked nose, sneezing, muscle pains, headache).
- Upper respiratory tract infection (sneezing, cough, runny nose, scratchy or sore throat, fever).
- Headache.

Less frequent side effects:

- Blood test results showing a reduced number of platelets.
- Drowsiness (or sleepiness).
- Constipation, stomach pain.
- Itching.
- Dizziness.

- Painful and stiff joints including osteoarthritis, pain in your hands, feet and legs.
- Decreased vitamin B_{12} and folic acid levels when blood tests are done.

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

- Joint pain, muscle pain, back pain or joint degeneration.

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 SALUMET.

5. How to store SALUMET

- Store at or below 25 °C.
- Keep the blister strips in the outer carton and keep the bottle well closed 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 SALUMET contains:

The active substances in SALUMET are sitagliptin and metformin.

SALUMET 50/500: Each film-coated tablet contains 50 mg sitagliptin (as sitagliptin phosphate anhydrous) and 500 mg metformin hydrochloride.

SALUMET 50/1 000: Each film-coated tablet contains 50 mg sitagliptin (as sitagliptin phosphate

anhydrous) and 1 000 mg metformin hydrochloride.

The other ingredients are: microcrystalline cellulose, croscarmellose sodium, povidone, hydroxypropyl cellulose, sodium stearyl fumarate, magnesium stearate.
SALUMET 50/500 contains Opadry II White (consisting of polyvinyl alcohol, titanium dioxide, macrogol and talc).

SALUMET 50/1 000 contains Opadry II Brown (consisting of polyvinyl alcohol, macrogol, titanium dioxide, talc, yellow iron oxide, red iron oxide and FD&C No. 6 Yellow/Sunset Yellow).

What SALUMET looks like and contents of the pack:
SALUMET 50/500: White to off-white, capsule shaped, biconvex, film-coated tablets, debossed with “663” on one side and plain on the other side.
SALUMET 50/1 000: Reddish brown coloured, capsule shaped, biconvex, film-coated tablets, debossed with “664” on one side and plain on the other side.

OPA/Alu/PVC/Alu blister strips containing 10 tablets each packed in an outer carton.
Or
White HDPE screw neck bottle with a white polypropylene child-resistant screw cap with liner.

Pack size: 30 or 60 tablets.
Not all pack sizes may be marketed.

Holder of certificate of registration:
Zydus Healthcare SA (Pty) Ltd
Southdowns Office Park
Building B, Ground Floor
22 Karee Street

Centurion, Pretoria

0157

Tel: 012 748 6400

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Not applicable.

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