PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

METJENTA 50/850 mg film-coated tablets

METJENTA 50/1 000 mg film-coated tablets

Sitagliptin and metformin hydrochloride

Sugar free.

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

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

1. What METJENTA is and what it is used for

METJENTA contains two different medicines, namely sitagliptin and metformin:

- Sitagliptin 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.

- Metformin belongs to a class of medicines called biguanides.

They work together to control blood sugar levels in adults with type 2 diabetes mellitus, by increasing the levels of insulin produced after a meal and lowering the amount of sugar made by your body.

Along with diet and exercise, METJENTA helps lower your blood sugar. METJENTA can be used alone or with certain other medicines for diabetes (insulin, sulphonylureas or glitazones).

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 like heart disease, kidney disease, blindness and amputation.

2. What you need to know before you take METJENTA

Do not take METJENTA:

- If you are hypersensitive (allergic) to sitagliptin, other gliptins, metformin or to any of the other ingredients of METJENTA listed in section 6 of this leaflet.
- 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 METJENTA and wait for at least 48 hours after this procedure, and for clearance from your doctor, before you start taking METJENTA 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 to excess (either every day or only from time to time).
- If you are breastfeeding.

Warnings and precautions

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

- Type 1 diabetes. You should not take METJENTA 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 METJENTA 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 METJENTA 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/she may want you to stop taking METJENTA for a short time.

Take special care with METJENTA if you:

- Are taking other medicines that lowers your blood sugar levels together with METJENTA (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.
- 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 METJENTA before the operation and for some time after the operation. Your doctor will decide when you must stop taking METJENTA and when you can start taking METJENTA again.
- Drink alcohol a lot (all the time or if you are short-term “binge-drinking”).
- Have a tendency to develop subnormal levels of vitamin B_{12}. METJENTA can interfere with vitamin B_{12} absorption and cause decreased serum vitamin B_{12} levels in your body.

Children and adolescents

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

Other medicines and METJENTA

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).
- Certain medicines for the treatment of high blood pressure (angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor antagonists).
- Specific medicines for the treatment of bronchial asthma (beta -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 human immunodeficiency virus (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 METJENTA.

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 METJENTA before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with METJENTA.

METJENTA with food, drink and alcohol

Avoid excessive alcohol intake while taking METJENTA, 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 METJENTA.

You should not take METJENTA if you are pregnant.

Do not take METJENTA if you are breastfeeding your baby.

Driving and using machines

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

Taking METJENTA 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 METJENTA

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

Always take METJENTA 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. If you have reduced kidney function, your doctor may prescribe a lower dose.

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

METJENTA alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When METJENTA 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 METJENTA will last. If you have the impression that the effect of METJENTA is too strong or too weak, tell your doctor or pharmacist.

If you take more METJENTA 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 require medical attention. Take this leaflet and the remaining METJENTA with you so the doctor will know what you have taken.

If you forget to take METJENTA

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 METJENTA

Continue to take METJENTA for as long as your doctor prescribes it. You should not stop taking METJENTA without talking to your doctor first. Your blood sugar levels may increase when you stop taking METJENTA.

4. Possible side effects

METJENTA can have side effects.

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

If any of the following happens, stop taking METJENTA 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 METJENTA. 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 (shortness of breath, more or less urine than is normal for you, confusion, drowsiness);
- 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), loss of appetite, metallic taste in your mouth.

Less frequent side effects:

- blood test results showing a reduced number of platelets;
- drowsiness (or sleepiness);
- diarrhoea, 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;
- decrease in blood sugar levels.

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

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

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. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of METJENTA.

5. How to store METJENTA

- Store at or below 30 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or blister strip.
- 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 METJENTA contains

The active substances in METJENTA are sitagliptin and metformin.

METJENTA 50/850: Each film-coated tablet contains sitagliptin phosphate monohydrate equivalent to 50 mg sitagliptin and 850 mg metformin hydrochloride.

METJENTA 50/1 000: Each film-coated tablet contains sitagliptin phosphate monohydrate equivalent to 50 mg sitagliptin and 1 000 mg metformin hydrochloride.

The other ingredients are: microcrystalline cellulose, Opadry II (consisting of polyvinyl alcohol, titanium dioxide, macrogol and talc), povidone, sodium laurilsulfate and magnesium stearate.

What METJENTA looks like and contents of the pack

METJENTA 50/850: White or almost white, capsule-shaped film-coated tablets, debossed with “L50” on one side and blank on the other side.

METJENTA 50/1 000: White or almost white, capsule-shaped film-coated tablets, debossed with “L72” on one side and blank on the other side.

Opaque white PVdC/PVC/Alu blister strips packed in an outer carton.

Pack size: 30 or 60 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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