TABLE OF CONTENTS – CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET

SEPTEMBER 2024

S.D.

CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET SEPTEMBER 2024

DO NOT USE [PRODUCT NAME] IF YOU HAVE TYPE 1 DIABETES.

There have been reports of metabolic acidosis, including ketoacidosis, in patients taking [PRODUCT NAME].

Metabolic acidosis is an imbalance of acids in your blood, shown on blood tests. It is a serious and sometimes fatal condition that requires hospitalization. Risk factors for metabolic acidosis include sudden decrease of your insulin dose, prolonged fasting from food and drink, or increasing your insulin dose due to major surgery or serious illness, or alcohol abuse. Caution is advised when using [PRODUCT NAME] if you have these conditions.

Diabetic ketoacidosis is a type of metabolic acidosis. Diabetic ketoacidosis is an increase of ketone bodies in your blood or urine, shown on blood or urine tests. Risk factors for diabetic ketoacidosis include pancreatic conditions, such as inflammation of the pancreas or previous pancreatic surgery. Do not use [PRODUCT NAME]if you have these conditions.

Metabolic acidosis, including diabetic ketoacidosis, may occur in patients with Type 2 diabetes mellitus with normal (blood glucose test result below 11 mmol/L) or high blood sugar levels who are treated with [PRODUCT NAME].

Contact a doctor or the nearest hospital straight away if you have the following symptoms even if your blood sugar levels are normal: nausea, vomiting, abdominal pain, fatigue, thirst, passing of large amounts of urine, shortness of breath and confusion. These symptoms could be a sign of metabolic or diabetic ketoacidosis.

S.D.

SCHEDULING STATUS:

S4

[PRODUCT NAME] 5 mg

[PRODUCT NAME] 10 mg

Dapagliflozin

[PRODUCT NAME] 5 mg contains 25 mg lactose monohydrate per tablet.

[PRODUCT NAME] 10 mg contains 50 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking [PRODUCT NAME]

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **[PRODUCT NAME]** 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

S.D.

1. What **[PRODUCT NAME]** is and what it is used for

[PRODUCT NAME] contains dapagliflozin.

It belongs to a group of medicines called “sodium glucose co-transporter-2 (SGLT2) inhibitors”. They work by blocking the SGLT2 protein in your kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from your body via the urine.

These are used to treat the following conditions:

[PRODUCT NAME] is used in adult patients (aged 18 years and older) to treat:

• Type 2 diabetes

- If your type 2 diabetes cannot be controlled with diet and exercise.
- **[PRODUCT NAME]** can be used on its own or together with other medicines to treat diabetes.

- [PRODUCT NAME] is used for prevention and treatment of heart failure (when the heart does not pump enough blood that the body needs).

• **[PRODUCT NAME]** is also used in patients with chronic kidney disease (reduced kidney function).

2. what you need to know before you take **[PRODUCT NAME]**

Do not take [PRODUCT NAME]:

If you are allergic to dapagliflozin or any of the other ingredients of this medicine listed in section 6

If you are pregnant plan to become pregnant. Talk with your doctor about the best way to control your blood sugar while you are pregnant.

If you are breastfeeding, talk to your doctor if you would like to breastfeed your baby.

If you have diabetes mellitus type 1 – the type that usually starts when you are young, and your body does not produce any insulin.

- If you have moderate or severe kidney disease or you are on dialysis.
- if you have a history of inflammation of the pancreas or pancreatic surgery.

S.D.

Warnings and precautions

Take special care with **[PRODUCT NAME]:**

- If you are going to have a surgery.
- If you are eating less due to illness or surgery, or you are dieting
- If you have or have had problems with your pancreas.
- If you drink large amounts of alcohol, either every day or only from time to time.
- If you develop any of the following symptoms, which may be signs of ketoacidosis: nausea, vomiting, stomach-area (abdominal) pain, tiredness, difficulty breathing, increased levels of "ketone bodies" in your blood or urine. If this happens to you contact a doctor or the nearest hospital immediately.
- If you have mild kidney disease your doctor will want to monitor your kidney function on an ongoing basis.
- If you often get infections of the urinary tract.
- If you are allergic to any other medicine used to lower the amount of sugar in your blood.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking **[PRODUCT NAME].**

Use in children and adolescents

The use of **[PRODUCT NAME]** in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and [PRODUCT NAME]

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any of the following medicines:

S.D.

- if you are taking a medicine used to remove water from the body (diuretic).
- if you have type 2 diabetes and are taking other medicines that lower the amount of sugar in your blood such as insulin or a “sulphonylurea” medicine. Your doctor may want to lower the dose of these other medicines, to prevent you from getting low blood sugar levels (hypoglycaemia).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **[PRODUCT NAME]**

Do not take **[PRODUCT NAME]** if you are pregnant or are breastfeeding.

Driving and using machines

[PRODUCT NAME] has no or negligible influence on the ability to drive and use machines.

Taking this medicine with other medicines called sulphonylureas or with insulin can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines.

Do not drive or use any tools or machines, if you feel dizzy taking **[PRODUCT NAME]**

[PRODUCT NAME] contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take [PRODUCT NAME]

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

Always take **[PRODUCT NAME]** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

S.D.

The recommended dose is one 10 mg tablet each day.

If you have the impression that the effect of **[PRODUCT NAME]** is too strong or too weak, talk to your doctor or pharmacist.

If you take more [PRODUCT NAME] than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take [PRODUCT NAME]

It is important to take your **[PRODUCT NAME]** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking [PRODUCT NAME]

If **[PRODUCT NAME]** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **[PRODUCT NAME]** for as long as your doctor has prescribed.

4. Possible side effects

Diabetic ketoacidosis (diabetic coma) and similar side effects may occur.

Symptoms are nausea, vomiting, abdominal pain, fatigue, thirst, passing of large volumes of urine, shortness of breath and mental confusion. Urgent medical attention is required.

[PRODUCT NAME] can have side effects.

Not all side effects reported for **[PRODUCT NAME]** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **[PRODUCT NAME]**, please consult your doctor, pharmacist or other healthcare professional for advice.

S.D.

If you have a hypersensitive (allergic) reaction, stop taking [PRODUCT NAME] and tell your doctor immediately or go to the casualty department of your nearest hospital.

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

- Very dry or sticky mouth, feeling very thirsty
- Feeling very sleepy or tired
- Passing little or no water (urine)
- Fast heart beat

These are signs of losing too much fluid from your body (volume depletion or dehydration.)

- Fever or chills
- Burning sensation when passing water (urinating)
- Pain in your back or side
- Blood in your urine, although uncommon

These are signs of a severe infection of the urinary tract.

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

Tell your doctor if you notice any of the following:

Frequent

- Low blood sugar levels (hypoglycaemia) – when taking this medicine with other medication or insulin to treat your diabetes.

These are signs of low blood sugar (hypoglycaemia):

- shaking, sweating, feeling very anxious, fast heart beat
- feeling hungry, headache, change in vision
- a change in your mood or feeling confused

Your doctor will tell you how to treat low blood sugar and what to do if you get any of the signs above.

- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)

S.D.

- back pain
- passing more water (urine) than usual or needing to pass water more often
- High sugar levels (glucose) in urine (shown in tests).
- changes in the amount of cholesterol or fats in your blood (shown in tests)
- Broken bones, if you already have moderate kidney problems.
- increases in the amount of red blood cells in your blood (shown in tests)
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment
- Dizziness
- rash

Less frequent:

- loss of too much fluid from your body (dehydration, signs may include very dry or sticky mouth, passing little or no urine or fast heartbeat)
- Increased thirst
- Constipation
- Itching of the genitals
- Increased sweating
- Tight foreskin which may cause difficulty urinating or inflammation of glans or foreskin (phimosis).
- Awakening from sleep at night to pass urine
- Dry mouth
- Weight decreased
- Increases in creatinine (shown in laboratory blood tests) in the beginning of treatment.
- Increases in urea (shown in laboratory tests)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Should your general health worsen or if you experience any untoward effects while taking **[PRODUCT NAME]**, please consult your healthcare provider for advice.

S.D.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. 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 **[PRODUCT NAME].**

5. How to store [PRODUCT NAME]

Store at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN.

Store in the original package / container

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister / label / carton bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What [PRODUCT NAME] contains

The active ingredient is dapagliflozin.

Contains sugar - lactose monohydrate

The other ingredients are:

Microcrystalline cellulose

Lactose monohydrate

Crospovidone

Sodium lauryl sulphate

Methylene chloride

S.D.

Colloidal silicon dioxide

Magnesium stearate

Insta moist shield Aqua II Yellow

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 5 mg: Each film-coated tablet contains 5 mg of dapaglifozin.

[PRODUCT NAME] 10 mg: Each film-coated tablet contains 10 mg of dapaglifozin.

Contents of the pack:

Tablets are packed in plain 25 micron aluminium foil and 25 micron OPA/ 45 micron aluminium foil/ 60 micron PVC on the other side.

Pack sizes include 10's, 14's; 28's; 30's; 90's and 98's tablets.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Ground Floor, Block 1,

Bassonia Estate Office Park (East),

Cussonia Drive,

Bassonia Rock Ext 12

Alberton

Gauteng

This leaflet was last revised in

19 SEPTEMBER 2024

Registration numbers

FARFLOZIN 5 mg: 56/21.2/0680

FARFLOZIN 10 mg: 56/21.2/0681

S.D.

DAPIFLO 5 mg: 56/21.2/0682.680

DAPIFLO 10 mg: 56/21.2/0683.681

Access to the corresponding Professional Information

The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

S.D.