Docusign Envelope ID: 2E93BF92-908D-4D32-90F4-5CC506F07796

Dr. Reddy's Laboratories (Pty) Ltd.
REDIFARG 5 & 10
PROPOSED CLEAN AMENDED PATIENT INFORMATION LEAFLET

Seq 0000: Submitted 30/09/2021
Response to Clinical recommendation received 04/03/2024: submitted 28/03/2024 (0004)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

REDIFARG 5, 5 mg, film-coated tablets

REDIFARG 10, 10 mg, film-coated tablets

Dapagliflozin

Sugar free

REDIFARG SHOULD ONLY BE USED IN THE TREATMENT OF TYPE 2 DIABETES. DO NOT TAKE REDIFARG FOR TYPE 1 DIABETES OR AS PART OF WEIGHT CONTROL PROGRAMMES.

Metabolic acidosis (when the body produces too much acid or the kidneys are not removing enough acid from the body), including ketoacidosis (high levels of acids, called ketones, in the blood), has occurred in patients taking REDIFARG, which may be serious and/or life-threatening.

If you experience nausea, vomiting, stomach pain, a general feeling of discomfort or illness, and shortness of breath, you should report to your doctor promptly, even if your blood sugar levels are below 14 mmol/L, as you may have metabolic acidosis. Your doctor will evaluate and manage your condition appropriately.

You may develop metabolic acidosis more easily if your insulin dose is reduced, your caloric/food intake is reduced, your intake of fluids is reduced or if you require more insulin due to infections, illness, surgery or with alcohol abuse. You should discuss these situations with your doctor while taking REDIFARG.

Do not take REDIFARG if you have disorders of the pancreas, e.g. a history of pancreatitis

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(inflammation in the pancreas) or pancreatic surgery, as you may develop ketoacidosis more easily.

Read all of this leaflet carefully before you start taking REDIFARG.

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

1. What REDIFARG is and what it is used for

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REDIFARG contains the active substance 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.

REDIFARG 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.
- REDIFARG can be used on its own or together with other medicines to treat diabetes.
- It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

2. What you need to know before you take REDIFARG

Do not take REDIFARG if:

- you are allergic (hypersensitive) to dapagliflozin or any of the other ingredients of REDIFARG (listed in Section 6).
- you have moderate or *severe* kidney disease, kidney failure or you are on dialysis.
- you have type 1 diabetes, the type that usually starts when you are young, and your body does not produce any insulin.
- you are pregnant or plan to become pregnant or if you are breastfeeding.
- you have a history of inflammation of the pancreas or pancreatic surgery.

Warnings and precautions:

Take special care with REDIFARG

Tell your doctor, pharmacist, or healthcare provider if the following apply to you or the following complications occur due to REDIFARG treatment:

- Check with your doctor or pharmacist if you are going to have any surgery.

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- If you have mild kidney disease your doctor will want to monitor your kidney function on an ongoing basis.
- If you have a severe liver function problem.
- If you are 65 years and older, as elderly are more likely to have impaired kidney function, to develop fluid loss/dehydration, or to be treated with medicines for high blood pressure that may cause changes in kidney function.
- If you develop any of the following symptoms, which may be signs of ketoacidosis: nausea, vomiting, stomach-area (abdominal) pain, tiredness, trouble breathing, increased levels of ketone bodies in your urine or blood. If this happens to you contact a doctor or the nearest hospital immediately.
- If you have type 2 diabetes mellitus and are taking other medicines that lower the amount of sugar in your blood.

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- If you have type 1 diabetes mellitus.
- If you develop a combination of symptoms of pain, tenderness, swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection. It is called necrotising fasciitis of the perineum or Fournier's gangrene which destroys the tissue under the skin. Fournier's gangrene has to be treated immediately.
- It is important for you to maintain preventative foot care to prevent the occurrence of lower limb amputation.
- If you are on medicines to lower your blood pressure (anti-hypertensives) or a water pill (diuretic) and have a history of low blood pressure (hypotension).
- 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 have any diabetic foot wounds, consult your doctor for foot care or to prevent the occurrence of lower limb amputation.
- If you have heart failure.
- If you often get infections of the urinary tract.
- If you are eating less due to illness or surgery, or you are dieting.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking REDIFARG.

Please note that you will test positive for glucose/sugar in your urine while you are taking REDIFARG.

Children and adolescents

REDIFARG is not recommended in children and adolescents younger than 18 years old as safety has not been established.

Other medicines and REDIFARG

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

Please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor if:

- You are taking a water pill (diuretic), you may be more likely to lose fluid from your body (get dehydrated). Your doctor may change your dose.
- You 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 your dose of these other medicines to stop you from getting low blood sugar (hypoglycaemia).
- Valsartan, used for high blood pressure or heart problems.
- Simvastatin, for the treatment of high blood cholesterol levels.
- Rifampicin, used for the treatment of tuberculosis (TB).
- Carbamazepine, phenytoin and phenobarbitone, used to treat epilepsy.
- Mefenamic acid, used for the treatment of pain.
- Digoxin, used for heart problems.
- Warfarin, a blood thinner.
- If you are monitoring the sugar in your urine, the 1,5-anhydroglucitol (1,5- AG) assay should not be used, as REDIFARG may interfere with the results.

REDIFARG with food and exercise

To control your diabetes, you still need to diet and exercise, even when you are taking this medicine. So, it is important to keep following the advice about diet and exercise from your health care professional, in particular, if you are following a diabetic weight control diet, keep on with this while you are taking REDIFARG.

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 this medicine.

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You should stop taking REDIFARG if you become pregnant or are breastfeeding your baby (see **Do not take REDIFARG**).

If you become pregnant while taking REDIFARG, report to your doctor as REDIFARG should not be taken while you are pregnant. Your doctor will prescribe different medicines to manage your blood sugar levels.

Driving and using machines

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

Do not drive or use any tools or machines, if you feel dizzy while taking REDIFARG.

3. How to take REDIFARG

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

Always take REDIFARG exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with REDIFARG will last.

Do not stop treatment early because your blood sugar may not be controlled.

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

How much to take:

- The usual dose is one 10 mg tablet every day.
- Your doctor will prescribe the strength that is right for you.

Taking this medicine:

- Swallow the tablet whole with half a glass of water.
- You can take your tablet with or without food.
- You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

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If your doctor has prescribed REDIFARG in combination with insulin or another medicine to treat high blood sugar levels, a lower dose of insulin or this other medicine may be required. Talk to your doctor if you are not sure how to take any of your medicines.

If you take more REDIFARG than you should

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

If you forget to take REDIFARG

Take your missed dose as soon as you remember, if within a few hours after missing a dose. However, if it is nearly time for your next dose, skip the missed dose. Then take your next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking REDIFARG

Do not stop taking REDIFARG without talking to your doctor first. If you have diabetes, your blood sugar may increase without this medicine.

4. Possible side effects

REDIFARG can have side effects.

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

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

- Allergic reactions, which may include a skin rash, fever, difficult breathing, wheezing, hives, itching, or swelling of the face, lips, or tongue (which may be life-threatening).
- Diabetic ketoacidosis, which may cause nausea, vomiting, loss of appetite, stomach pain, a general feeling of discomfort or illness, excessive thirst, difficult breathing, confusion and unusual fatigue or sleepiness (see **Warnings and precautions**).

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- **Necrotising fasciitis of the perineum** or Fournier's gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus.

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

Those that occur frequently:

- Female genital infection or inflammation, which may cause irritation, redness, itching, discharge, unpleasant odour/smell, burning and discomfort while urinating, swelling and rash.
- Male genital infection or inflammation, which may cause irritation, redness, itching, discharge, unpleasant odour/smell, burning and discomfort while urinating, swollen glands and soreness.
- Urinary tract infection, including inflammation of the kidney (pyelonephritis), bladder infection (cystitis), which may cause fever, back pain, nausea, vomiting, cloudy, dark urine or blood in the urine, burning urine and frequent urination.
- Low blood sugar (hypoglycaemia), when used with other medicines to treat high blood sugar levels, which may cause you to feel shaky, dizzy, hungry, or tired.

Those that occur less frequently:

- Dehydration, decreased blood volume (hypovolaemia), or low blood pressure (hypotension), and thirst, which may cause a rapid heartbeat, decreased or no urination, shallow breathing, weakness, dizziness or fainting.

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

Tell your doctor if you notice any of the following:

Frequent:

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- Genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour).
- Back pain.
- Passing more water (urine) than usual or needing to pass water more often.
- Changes in the amount of cholesterol or fats in your blood (shown in tests).
- 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:

- Fungal infection, which may cause an itchy red rash that may form a circular / ring shape or flaking skin.
- Constipation.
- Dry mouth.
- Excessive sweating.
- 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).
- Thirst.
- Awakening from sleep at night to pass urine.
- Weight decreased.
- Increases in creatinine (shown in laboratory blood tests) in the beginning of treatment.
- Increases in urea (shown in laboratory blood tests).

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the

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"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 REDIFARG.

5. How to store REDIFARG

Store at or below 25 °C.

Keep the container well closed.

This medicine does not require any special storage conditions.

Do not store in a bathroom.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

Do not use after the expiry date stated on the carton.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What REDIFARG contains

The active substance is dapagliflozin.

REDIFARG 5: Each film-coated tablet contains 5 mg dapagliflozin.

REDIFARG 10: Each film-coated tablet contains 10 mg dapagliflozin.

The other ingredients are Colloidal silicon dioxide, Crospovidone (Polyplasdone XL), Magnesium stearate, Microcrystalline cellulose (Avicel PH 102), Sodium lauryl sulphate.

The film-coat (Opadry II yellow) ingredients are Iron Oxide Yellow, Macrogol/PEG, Polyvinyl alcohol, Talc, Titanium Dioxide.

What REDIFARG looks like and contents of the pack

REDIFARG 5: yellow coloured, round, biconvex, film-coated tablets debossed with "D1" on one side and "M" on other side.

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REDIFARG 10: yellow coloured, diamond, biconvex, film-coated tablets debossed with "D2" on one side and "M" on other side.

REDIFARG 5:

- HDPE (60 cc) container, contains 30 tablets.
- HDPE (150 cc) container, contains 500 tablets.
- Aluminium lidding foil on another side in the form of a Alu-Alu blister pack and such 3 X 10 blisters are further packed in printed carton along with instructions for use, contains 30 tablets.

REDIFARG 10:

- HDPE (60 cc) container, contains 30 tablets.
- HDPE (150 cc) container, contains 500 tablets.
- Aluminium lidding foil on another side in the form of a Alu-Alu blister pack and such 3 X 10 blisters are further packed in printed carton along with instructions for use, contains 30 tablets.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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South Africa

This leaflet was last revised in

To be allocated

Registration number

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REDIFARG 5: To be allocated **REDIFARG 10:** To be allocated
For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100
Access to the corresponding Professional Information Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: http://www.drreddys.co.za