

**Dr. Reddy's Laboratories (Pty) Ltd.
REDIFARG XR 5 mg/ 500 mg
REDIFARG XR 5 mg/ 1000 mg
REDIFARG XR 10 mg/ 500 mg
REDIFARG XR 10 mg/ 1000 mg
APPROVED PATIENT INFORMATION LEAFLET**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

REDIFARG XR 5 mg/ 500 mg

REDIFARG XR 5 mg/ 1000 mg

(Dapagliflozin / Metformin hydrochloride)

(Contains sugar – lactose 108,950 mg)

REDIFARG XR 10 mg/ 500 mg

REDIFARG XR 10 mg/ 1000 mg

(Dapagliflozin / Metformin hydrochloride)

(Contains sugar – lactose 103,950 mg)

Extended-release tablets

Risk of metabolic acidosis

REDIFARG XR may cause a very rare, but very serious side effect called metabolic acidosis, particularly if your kidneys are not working properly. The risk of developing metabolic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information 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). If any of the above apply to you, talk to your doctor for further instructions.

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

- 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.

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

1. What REDIFARG XR is and what it is used for

This medicine contains dapagliflozin and metformin as active substances. Both belong to a group of medicines called oral anti-diabetics. These are medicines taken by mouth for treatment of diabetes.

REDIFARG XR is used for a type of diabetes called "Type 2 diabetes" in adult patients (aged 18 years and older).

Type 2 diabetes usually occurs when you are older. If you have Type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use the insulin it produces properly. This leads to a high level of sugar (glucose) in your blood.

- Dapagliflozin works by removing excess sugar from your body via your urine and lowers the amount of sugar in your blood.
- Metformin works mainly by inhibiting glucose production in the liver.

To treat diabetes:

- This medicine is taken in combination with diet and exercise.
- This medicine is used if your diabetes can be controlled with a combination of dapagliflozin and metformin.

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- Your doctor may ask you to take this medicine on its own or together with other medicines to treat diabetes.

2. What you need to know before you take REDIFARG XR

Do not take REDIFARG XR

- if you are hypersensitive (allergic) to dapagliflozin, metformin or any of the other ingredients of REDIFARG XR (see section 6).
- if you have severe kidney impairment.
- if you have uncontrolled diabetes, with, for example severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, metabolic acidosis. Metabolic acidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to a diabetic pre-coma.
- if you have diabetes mellitus type 1.
- if you are pregnant or 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.

Warnings and precautions

Special care should be taken with REDIFARG XR.

- if you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, contact a doctor or the nearest hospital straight away. These symptoms together could be a sign of "diabetic metabolic acidosis" – a problem you can get with diabetes because of increased levels of "ketone bodies" in your urine or blood, seen in tests. The risk of developing diabetic metabolic acidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden

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reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.

- if you experience vomiting, stomach-ache (abdominal pain), muscle cramps, a general feeling of not being well with severe tiredness, difficulty in breathing, reduced body temperature and heartbeat. These symptoms together could be a sign of “metabolic acidosis” – a very rare, but very serious side effect, particularly if your kidneys are not working properly. The risk of developing metabolic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as severe heart disease).
- if you have problems with your kidneys.
- if you have liver problems.
- if you have very high levels of glucose in your blood which may make you dehydrated (lose too much body fluid). Possible signs of losing too much fluid from your body are listed in section 4. Tell your doctor before you start taking this medicine if you have any of these signs.
- if you are taking medicines to lower blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). More information is given in the section “Taking other medicines with REDIFARG XR”.
- if you have a history of serious heart disease or if you have had a stroke.
- if you often get infections of the urinary tract. This medicine may cause urinary tract infections and your doctor may want to monitor you more closely. Your doctor may consider temporarily changing your treatment if you develop a serious infection.
- if you are older than 65 years you may be at a greater risk for volume depletion and impaired kidney function. Temporary interruption or a lower starting dose may be required if you develop volume depletion.
- if you are taking another medicine for diabetes such as insulin or sulfonylureas.
- if you have an increase in the amount of red blood cells in your blood, seen in blood tests.
- if you are going to have surgery. Your doctor will decide when you must stop and when to restart

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your treatment with REDIFARG XR.

- If you have symptoms of pain, tenderness, erythema, or swelling in the genital or perineal area, with fever or malaise. Be aware that either uro-genital infection or perineal abscess may precede necrotising fasciitis (Fournier's gangrene). You may also have an increased risk of urinary tract infections.
- You may have a higher risk for lower limb amputations. Routine preventative foot care is important.
- If you drink excessive amounts of alcohol.

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

Surgical procedures

Tell your anaesthetist and surgeon that you are taking REDIFARG XR. REDIFARG XR should be temporarily suspended before any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until your doctor says so. You may require insulin during the operation.

Children and adolescents

REDIFARG XR is not recommended for children or young people under 18 years old.

Other medicines and REDIFARG XR

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may adjust the dosage of REDIFARG XR. It is especially important to mention the following:

- if you are taking medicines which increase urine production (diuretics). Possible signs of losing too much fluid from your body are listed in section 4.
- if you are taking other medicines that lower the amount of sugar in your blood such as insulin or a

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“sulphonylurea” medicine. Your doctor may want to lower the dose of these other medicines, to prevent you from getting blood sugar levels that are too low (hypoglycaemia).

- if you are taking cimetidine, a medicine used to treat stomach problems.
- if you are using bronchodilators (beta-2 agonists) which are used to treat asthma.
- if you are using corticosteroids, which are used to treat inflammation in diseases like asthma and arthritis.
- if you are using medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- if you are using certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- If you are using radio medicines like iodinated contrast medicines.

REDIFARG XR with food and drink and alcohol

Avoid excessive alcohol intake while taking REDIFARG XR since this may increase the risk of metabolic acidosis.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking REDIFARG XR. You should stop taking this medicine if you become pregnant, since you should not use this medicine during pregnancy. Talk to your doctor about the best way to control your blood sugar while you are pregnant.

Talk to your doctor if you would like to or are breastfeeding before taking this medicine. You should not use this medicine if you are breastfeeding. It is not known if this medicine passes into human breast milk.

Driving and using machines

REDIFARG XR has no or negligible influence on the ability to drive and use machines. Taking this medicine with other medicines or insulin used to treat your diabetes can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as weakness, dizziness, increased sweating, fast

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heartbeat, change in vision or difficulties concentrating, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you start to feel these symptoms.

REDIFARG XR contains lactose

REDIFARG XR contains lactose (which is a type of sugar).

Patients with the rare hereditary conditions of lactose intolerance should not take REDIFARG XR.

3. How to take REDIFARG XR

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

Always take REDIFARG XR 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:

REDIFARG XR 5 mg/ 500 mg - take one or two tablets once in the evening.

REDIFARG XR 5 mg/ 1000 mg – take one or two tablets once in the evening.

REDIFARG XR 10 mg/ 500 mg – take one tablet once in the evening.

REDIFARG XR 10 mg/ 1000 mg – take one tablet once in the evening.

The amount of REDIFARG XR that you will take varies depending on your condition and the doses you currently take of metformin and/or individual tablets of dapagliflozin and metformin. Your doctor will tell you exactly which strength of this medicine to take.

Swallow the whole tablet with half a glass of water. Never crush, cut or chew the tablet.

Take your tablet with food. This is to reduce the risk of side effects in the stomach.

Occasionally, the inactive ingredients of REDIFARG XR will be eliminated in the faeces as a soft, hydrated mass that may resemble the original tablet.

Your doctor and pharmacist will tell you how long your treatment with REDIFARG XR will last. Do not stop treatment early. If you have the impression that the effect of REDIFARG XR is too strong or too weak, tell your doctor or pharmacist.

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If you take more REDIFARG XR than you should

If you realise that you have taken more REDIFARG XR than you should, you may experience lactic acidosis.

Symptoms of lactic acidosis include feeling or being very sick, vomiting, stomach-ache, muscular cramps, severe tiredness or difficulty breathing. If this happens to you, you may need immediate hospital treatment, as metabolic acidosis may lead to coma. Stop taking this medicine immediately and contact a doctor or the nearest hospital straight away. Take the medicine pack with you.

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 XR

Do not take a double dose of this medicine to make up for a forgotten dose.

If you stop taking REDIFARG XR

Do not stop taking this medicine without talking to your doctor first. Your blood sugar may increase without this medicine.

If you have any further questions on the use of this product, ask your doctor, pharmacist or other healthcare provider.

4. Possible side effects

REDIFARG XR can have side effects.

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

If any of the following happens, stop taking REDIFARG XR and tell your doctor, pharmacist or healthcare provider immediately or go to the casualty department at your nearest hospital.

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,

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- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to REDIFARG XR. You may need urgent medical attention or hospitalisation.

- very dry or sticky mouth, feeling very thirsty,
- feeling very sleepy or tired,
- passing little or no water (urine) and fast heartbeat.

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

- vomiting,
- stomach ache (abdominal pain),
- muscle cramps,
- a general feeling of not being well with severe tiredness,
- difficulty in breathing and reduced body temperature and heartbeat.

These are signs of metabolic acidosis. Metabolic acidosis may lead to coma and death.

- fever or chills,
- burning sensation when passing water (urinating),
- pain in your back or side and
- blood in your urine, although uncommon.

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

- increased levels of “ketone bodies” in your urine or blood (shown on urine or blood tests),
- rapid weight loss,
- feeling sick or being sick,
- stomach pain,
- excessive thirst,

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- fast and deep breathing,
- confusion,
- unusual sleepiness or tiredness,
- a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat.

These are the signs of diabetic metabolic acidosis. This may occur regardless of blood glucose level.

Your doctor may decide to temporarily or permanently stop your treatment with REDIFARG XR.

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

Tell your doctor if you notice any of the following

The following side effects have been reported frequently:

- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour).
- low blood sugar levels (hypoglycaemia) - when taking this medicine with other medication or insulin to treat your diabetes.
- changes in taste.
- dizziness.
- rash or itching.
- passing more water (urine) than usual or needing to pass water more often.
- discomfort when passing water (urine).
- nausea.
- vomiting.
- diarrhoea or stomach-ache.
- loss of appetite.
- back pain.
- changes in the amount of cholesterol or fats in your blood (shown in tests).

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- changes in the amount of red blood cells in your blood (shown in tests).
- changes in laboratory blood tests (creatinine or urea).

The following side effects have been reported less frequently:

- thirst.
- constipation.
- dry mouth.
- fungal infections.
- an infection with rapid progression that causes severe tissue destruction.
- decreased vitamin B12 levels in the blood.
- abnormalities in liver function tests, inflammation of the liver (hepatitis).
- redness of the skin (erythema), itching or an itchy rash (hives).
- awakening from sleep at night to pass urine.
- skin infections affecting female genitalia.
- decreased weight.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or health care professional. 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 website.

By reporting side effects, you can help provide more information on the safety of REDIFARG XR.

5. How to store REDIFARG XR

Store at or below 25 °C.

Do not store in a bathroom.

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

Keep the container tightly closed until required for use.

Keep the tablets in the blisters and the blisters in the outer carton until required for use.

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

Return all unused and expired medicines to your pharmacist.

Keep all medicines out of reach and sight of children.

6. Contents of the pack and other information

What REDIFARG XR contains

The active substances are dapagliflozin and metformin hydrochloride.

REDIFARG XR 5 mg/ 500 mg:

Each extended-release tablet contains 5 mg dapagliflozin and 500 mg metformin hydrochloride.

REDIFARG XR 5 mg/ 1000 mg:

Each extended-release tablet contains 5 mg dapagliflozin and 1000 mg metformin hydrochloride.

REDIFARG XR 10 mg/ 500 mg:

Each extended-release tablet contains 10 mg dapagliflozin and 500 mg metformin hydrochloride.

REDIFARG XR 10 mg/ 1000 mg:

Each extended-release tablet contains 5 mg dapagliflozin and 1000 mg metformin hydrochloride.

The other ingredients are crospovidone XL, hypromellose, iron oxide, isopropyl alcohol, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry II purple, Opadry II white, purified water, silicon dioxide, sodium carboxy methyl cellulose, sodium lauryl sulfate.

What REDIFARG XR looks like and contents of the pack

REDIFARG XR 5 mg/ 500 mg:

Light pink coloured, capsule shaped biconvex, film-coated tablets debossed with "MD6" on one side and plain on other side.

REDIFARG XR 5 mg/ 1000 mg:

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Light pink coloured, oval shaped, biconvex, film-coated tablets debossed with "MD5" on one side and plain on other side.

REDIFARG XR 10 mg/ 500 mg:

Brown coloured, capsule shaped, biconvex, film-coated tablets debossed with "MD7" on one side and plain on other side.

REDIFARG XR 10 mg/ 1000 mg:

Brown coloured, oval shaped, biconvex, film-coated tablets debossed with "MD4" on one side and plain on other side.

HDPE Bottle 30's Pack

REDIFARG XR 5/ 500 mg; 10/ 500 mg:

75 cc white opaque HDPE containers closed with induction sealing wads with a 2 gm silica gel canister in the bottle.

REDIFARG XR 5/ 1000 mg; 10/ 1000 mg:

100 cc white opaque HDPE containers closed with induction sealing wads with a 2 gm silica gel canister in the bottle.

PVC/Aclar Alu Blister pack 10's / 30's / 60's

REDIFARG XR 5/ 500 mg; 10/ 500 mg:

Aluminium base foil on one side and Aluminium lidding foil on another side in the form of a PVC/Aclar Alu blister pack.

REDIFARG XR 5/ 1000 mg; 10/ 1000 mg:

Aluminium base foil on one side and Aluminium lidding foil on another side in the form of a PVC/Aclar Alu blister pack.

Not all strengths and pack sizes may be marketed.

Holder of Certificate of Registration

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REDIFARG XR 5/ 500 mg: 57/21.2/0885

REDIFARG XR 5/ 1000 mg: 57/21.2/0886

REDIFARG XR 10/ 500 mg: 57/21.2/0887

REDIFARG XR 10/ 1000 mg: 57/21.2/0888

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>