PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

DIAMET XR 500 extended release tablets

DIAMET XR 750 extended release tablets

DIAMET XR 1000 extended release tablets

Metformin hydrochloride

Sugar Free

Read all of this leaflet carefully before you start taking DIAMET 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.
- **DIAMET 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 DIAMET XR is and what is it used for:**

DIAMET XR extended release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of Type 2 (non-insulin dependent) diabetes mellitus.

DIAMET XR is used for the treatment of Type 2 diabetes when diet and exercise changes alone have not been enough to control blood glucose (sugar). Insulin is a hormone that enables body tissues to take glucose from the blood and to use it for energy or for storage for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long-term problems, so it is important that you continue to take your medicine, even

though you may not have any obvious symptoms. DIAMET XR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

DIAMET XR extended release tablets are specially made to release the drug slowly in your body and therefore are different to many other types of tablets containing metformin.

2. **What you need to know before you take DIAMET XR:**

Do not take DIAMET XR if:

- you are allergic to metformin or to any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a rash, itching or shortness of breath.
- you have liver problems.
- you have severely reduced kidney function.
- you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see ‘Risk of lactic acidosis’ below) or ketoacidosis. Ketoacidosis is a condition in which substances called ‘ketone bodies’ accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual, fruity smell.
- you have lost too much water from your body (dehydration). Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- you have a severe infection, such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- you have been treated for acute heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- you are a heavy drinker of alcohol.
- you are pregnant.

Warnings and precautions

Risk of lactic acidosis.

DIAMET XR may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic 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. Stop taking DIAMET XR for a short time if you have a 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. Stop taking DIAMET XR and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

• 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

Lactic acidosis is a medical emergency and must be treated in a hospital.

If you need to have major surgery you must stop taking DIAMET XR during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with DIAMET XR. During treatment with DIAMET XR, 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.

If you have heart problems but your condition is under control, your doctor will monitor your heart function regularly.

If you are older than 75 years, treatment with DIAMET XR should not be started to lower the risk of developing type 2 diabetes.

You may see some remains of the tablets in your stools. Do not worry- this is normal for this type of tablet. You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat carbohydrates regularly throughout the day.

Do not stop taking this medicine without speaking to your doctor.

This medicine contains less than 1mmol sodium (23mg) per dosage unit, that is to say it is essentially 'sodium free'

Children and adolescents

DIAMET XR is not for use in children and adolescents under 18 years of age.

Other medicines and DIAMET XR:

Tell your doctor if you are taking, have recently taken or might take any other medicines (this includes all complementary or traditional medicines). You may need

more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of DIAMET XR. It is especially important to mention the following:

• Medicines which increase urine production (diuretics (water tablets) such as furosemide.

• Medicines used to treat pain and inflammation (NSAID and COX-2 inhibitors, such as ibuprofen and celecoxib)

• Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)

• Steroids such as prednisolone, mometasone, beclometasone.

• Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure. Epinephrine is also included in some dental anaesthetics.

• Medicines that may change the amount of DIAMET XR in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole,

crizotinib, olaparib).

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

DIAMET XR with food, drink, and alcohol:

Avoid excessive alcohol intake while taking DIAMET XR since this may increase the risk of lactic acidosis (see section 'Warnings and precautions').

DIAMET XR may be taken with or without food.

Pregnancy and breastfeeding and fertility:

Do not take DIAMET XR if you are pregnant or breast feeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please ask your doctor, pharmacist or other health care provider for advice before taking DIAMET XR.

Driving and using machines:

DIAMET XR taken on its own does not cause 'hypos' (symptoms of low blood sugar or hypoglycaemia, such as faintness, confusion and increased sweating) and therefore should not affect your ability to drive or use machinery. You should be aware, however, that DIAMET XR taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

It is not always possible to predict to what extent DIAMET XR may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DIAMET XR affects you.

3. How to take DIAMET XR:

Do not share medicines prescribed for you with any other person.
Your doctor may prescribe DIAMET XR for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Always take DIAMET XR exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water, do not chew.

The usual dose is:

DIAMET XR 500

The usual starting dose is one tablet daily taken with the evening meal. Your doctor may adjust your dose after 10 to 15 days. The maximum recommended dosage is usually not more than 4 tablets daily.

DIAMET XR 750

The usual starting dose is one tablet daily taken with the evening meal. Your doctor may adjust your dose after 10 to 15 days. The maximum recommended dosage is usually not more than 2 tablets daily.

DIAMET XR 1000

The usual starting dose is one tablet daily taken with the evening meal at a maximum recommended dose of 2 tablets per day. DIAMET XR 1000 is intended as maintenance therapy for patients currently treated either 1000 mg or 2000 mg of metformin hydrochloride.

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

If you take more DIAMET XR than you should:

If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis is more likely. Symptoms of lactic acidosis are non-specific, such as vomiting, bellyache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat. If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma.

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 a dose of DIAMET XR:

Try to take **DIAMET XR** as prescribed by your healthcare professional. However, if you miss a dose, do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DIAMET XR can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Difficulty breathing, dizziness (severe hypersensitivity).

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

If any of the following happens, tell your doctor immediately or go to the nearest hospital immediately.

- DIAMET XR may cause a less frequent but very serious side effect called lactic acidosis (see section 'Warnings and precautions')
- DIAMET XR may cause abnormal liver function tests and
- hepatitis (inflammation of the liver) which may result in jaundice. If you develop yellowing of the eyes and/or skin contact your doctor immediately.
- Hypoglycaemia (very low blood sugar levels).

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

Tell your doctor if you notice any of the following:

Frequent:

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. If you get these, do not stop taking the tablets as these symptoms will normally go away in about 2 weeks. It helps if you take the tablets with or immediately after a meal.
- Taste disturbance

Less Frequent:

- Decreased vitamin B12 levels
- Skin rashes including redness, itching and hives.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. 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 **DIAMET XR**.

5. How to store DIAMET XR

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

Store **DIAMET XR** at or below 30 °C in an outer carton. Protect from moisture.

Do not use this medicine after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What DIAMET XR contains:

The active substance is Metformin Hydrochloride

The other ingredients are: Carmellose sodium, hypromellose, magnesium stearate, silica colloidal anhydrous**.**

What DIAMET XR looks like and contents of the pack

DIAMET XR 500mg Extended Release Tablets:

White to off-white, capsule shaped tablet debossed with ‘SR 500’ on one side and plain on other side**.**

DIAMET XR 750mg Extended Release Tablets:

White to off-white, capsule shaped tablet debossed with ‘SR 750’ on one side and plain on other side.

DIAMET XR 1000mg Extended Release Tablets:

White to off-white, oval tablet debossed with ‘SR 1000’ on one side and plain on other side.

Contents of the pack

DIAMET XR 500mg Extended Release Tablets:

30’s, 56’s, 60’s or 90’s- DIAMET XR is packed in cartons containing 10 or 14 tablets packed in an aluminium foil blister 0.02 mm x 198 mm & a transparent PVC film 0.35 mm x 202 mm

DIAMET XR 750mg Extended Release Tablets:

30’s or 60’s- DIAMET XR is packed in cartons containing 10 tablets packed in an aluminium foil blister 0.02 mm x 198 mm & a transparent PVC film 0.35 mm x 202 mm

DIAMET XR 1000mg Extended Release Tablets:

30's, 56's, or 60's- DIAMET XR is packed in cartons containing 10 or 14 tablets packed in an aluminium foil blister 0.02 mm x 198 mm & a transparent PVC film 0.35 mm x 202 mm

Holder of Certificate of Registration

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2091

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DIAMET XR 500 : 57/21.2/0121

DIAMET XR 750: 57/21.2/0122

DIAMET XR 1000: 57/21.2/0123

Access to the corresponding Professional information.

Is either contained in the packaging, alternatively follow the link for the

corresponding Professional Information for Diamet XR:

pi-pil-repository.innovata.co.za,

or please scan the QR code below:

PLACE HOLDER:

The QR code to be included after approval.