PATIENT INFORMATION LEAFLET FOR

DIAPHAGE 500 / 850 / 1000

SCHEDULING STATUS: S3

DIAPHAGE 500 mg, film-coated tablet

DIAPHAGE 850 mg, film-coated tablet

DIAPHAGE 1000 mg, film-coated tablet

Metformin Hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking DIAPHAGE

- 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.
- DIAPHAGE 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 DIAPHAGE is and what it is used for
2. What you need to know before you take DIAPHAGE
3. How to take DIAPHAGE
4. Possible side effects
5. How to store DIAPHAGE

6. Contents of the pack and other information.

1. What DIAPHAGE is and what it is used for

DIAPHAGE is indicated for the treatment of type 2 diabetes mellitus. Metformin, the active ingredient in DIAPHAGE, helps to bring your blood glucose levels down by making your cells more sensitive to insulin and also possibly by delaying absorption of glucose from your gut and by decreasing your liver's production of glucose.

DIAPHAGE can be used by adults with type 2 diabetes mellitus as single agent to control their disease, or in combination with other oral antidiabetic medicines or injectable insulin. Children older than 12 years and teenagers with type 2 diabetes may also use DIAPHAGE as single agent or in combination with insulin.

2. What you need to know before you take DIAPHAGE

Do not take DIAPHAGE:

- if you are hypersensitive (allergic) to metformin or any of the other ingredients of DIAPHAGE (listed in **section 6**).
- if you suffer from any type of metabolic acidosis (too much acid is in your body) such as lactic acidosis ('see Warnings and Precautions') or diabetic ketoacidosis (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.
- if you suffer from diabetic pre-coma (dangerously high blood sugar or dangerously low blood sugar).

- if you suffer from any of the following conditions:
    - Dehydration
    - Severe infection
    - Shock (poor blood circulation with very low blood pressure)
    - Heart or lung failure
    - Recent heart attack
    - Any disease of your pancreas
    - Liver disease
    - Alcoholism, or if you are a heavy drinker of alcohol.
- if you are scheduled for x-ray, CT-scan or MRI-scan examinations that require the use of intravenous dye (contrast agent) that contains iodine. Please discuss with your doctor if you are unsure.
- if you are pregnant or breast-feeding, or if you are planning to become pregnant.
- if your child suffers from type 1 diabetes mellitus (insulin-dependent diabetes).

Warnings and precautions

Take special care with DIAPHAGE:

Before using DIAPHAGE you should speak to your doctor if you:

- Suffer from impaired kidney function or any kidney disease. Your doctor may need to test your kidney function while you are taking DIAPHAGE.
- Are scheduled for surgery. Inform your doctor at least 48 hours before going for surgery as your doctor may need to temporarily stop your treatment until/after the surgery.

Risk of Lactic acidosis:

DIAPHAGE may cause a very rare, but very serious side effect called lactic acidosis. that most often occurs if your kidneys or blood circulation system are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, ketosis, prolonged fasting, excessive alcohol intake, liver problems or any medical conditions in which a part of the body has a reduced supply of oxygen (such as a sudden onset severe heart disease) as well as certain medication (see 'Other medicines and DIAPHAGE).

In case of dehydration (if you lost too much water from your body, due to long-lasting or severe diarrhoea, or if you have vomited several times in a row or have insufficient fluid intake) DIAPHAGE should be briefly stopped and you should contact your healthcare professional.

Medication such as certain blood pressure medicine, medicine that increases urine output (diuretics), and anti-inflammatory medicine can cause sudden kidney problems and should be used with caution. Inform your healthcare provider if you are taking any such medicine.

Lactic acidosis is a medical emergency which must be treated in hospital. Symptoms of lactic acidosis include:

- vomiting
- stomach-ache
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduces body treatment and heartbeat.

All patients on DIAPHAGE require regular clinical and blood examinations to ensure that their condition is well-controlled. All patients should continue their diabetic diet with regular meals during the day. Overweight patients should continue their energy-restricted diet.

You will have to undergo periodic blood tests to ensure that your blood glucose levels are within normal limits and that your kidneys are still functioning properly.

Taking medicine than contains iodine:

Stop taking DIAPHAGE for a short period if you are going to receive medicine containing iodine used for x-ray-based imaging. Your doctor will decide when you must stop and when to restart your treatment with DIAPHAGE.

Surgery:

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

Other Precautions:

You should continue with a balanced diet which consists of regular distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet.

The usual tests for diabetes monitoring should be performed regularly.

DIAPHAGE on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take DIAPHAGE together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia.

Do not take DIAPHAGE if you are suffering from conditions which may cause dehydration, serious infections, trauma or on low calorie intake (see ‘Do not take DIAPHAGE).

If you are on long-term DIAPHAGE treatment, your Vitamin B12 levels should be checked at least once a year since DIAPHAGE may cause mal absorption of Vitamin B12, which may result in a disease called megaloblastic anaemia (lack of enough red blood cells to carry adequate oxygen to your body's tissue which can make you feel weak and tired) (See 'Possible side-effects').

Children and adolescents

Children older than 12 years and adolescents who use DIAPHAGE will have to undergo periodic examinations to ensure that they are growing and developing normally. The diagnosis of type 2 diabetes mellitus must be confirmed before treatment with DIAPHAGE is initiated.

Other medicines and DIAPHAGE

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

Concomitant use not recommended.

Iodinated contrast medicine – the use of contrast medicine that contains iodine given to you if you are going for an x-rays may lead to renal failure and lactic acidosis.

Combinations requiring precaution for use

- 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).
- medicines which increase urine production (diuretics)

- glucocorticoids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)
- medicines that may change the amount of DIAPHAGE in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib)

DIAPAHGE with food, drink and alcohol

DIAPHAGE should be taken with or after meals

- You should eat carbohydrates regularly throughout the day.
- You should not skip meals.
- You need to follow your doctor's/nutritionist's advice regarding your diet very carefully.

Avoid consumption of alcohol and alcohol-containing medicine since this may increase the risk of lactic acidosis (see Warnings and precautions).

Pregnancy, breastfeeding and fertility

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 DIAPHAGE.

Do not use DIAPHAGE if you are pregnant or breastfeeding your baby.

Driving and using machines

When your blood glucose levels fall too low, you may feel faint, dizzy, confused, sweaty and nauseous. You should not drive or use tools or machines if your blood glucose levels are too low. This can sometimes happen when DIAPHAGE is combined with other medicines or with insulin (see "Other medicines and DIAPHAGE"). Do not drive or operate machinery before you know how DIAPHAGE will affect you.

It is not always possible to predict to what extent DIAPHAGE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DIAPHAGE affects them.

If you forget to take DIAPHAGE:

Always take DIAPHAGE as prescribed. If you miss a dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose. It is important to take DIAPHAGE regularly, because irregular intake may increase the risk of developing too high blood glucose levels with all its associated complications.

3. How to take DIAPHAGE

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

Always take DIAPHAGE exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

DIAPHAGE should be taken in divided doses with meals.

The usual dose is:

Adults:

- Initially, one 500 mg tablet two to three times a day, or one 850 mg or 1000 mg tablet twice a day (mornings and evenings), with or after food.
- After 10 to 15 days your doctor may change the dose based on measurements of your blood glucose levels.

Elderly patients:

Your doctor will change your dose depending on your kidney function.

Children > 12 years and adolescents:

- Initially, one 500 mg or one 850 mg tablet once daily, with or after meals.
- After 10 to 15 days your doctor may change the dose based on measurements of your blood glucose levels.

Your doctor will tell you how long your treatment with DIAPHAGE will last. If you have the impression that the effect of DIAPHAGE is too strong or too weak, talk to your doctor or pharmacist.

If you take more DIAPHAGE than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience side-effects such as those listed below.

The most dangerous side-effect from overdosage is lactic acidosis, which can be life-threatening.

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

If you forget to take DIAPHAGE:

Always take DIAPHAGE as prescribed. If you miss a dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten individual dose. It is important to take DIAPHAGE as prescribed by your doctor, because irregular intake may increase the risk of developing too high blood glucose levels with all its associated complications.

4. Possible side effects

DIAPHAGE can have side-effects.

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

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

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

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

- Lactic acidosis. This is a less frequent but serious complication particularly if your kidneys are notworking properly. Symptoms of lactic acidosis are non-specific (see Warning and precautions).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- low Vitamin B12 levels and folic acid in the blood.
- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- abdominal pain (belly pain)
- loss of appetite.

These side effects most often happen at the beginning of the treatment with DIAPHAGE. It helps if you spread the doses over the day and if you take DIAPHAGE with or straight after a meal.

- constipation
- taste disturbances such as metallic taste

Less frequent side effects:

- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
- lack of enough red blood cells to carry adequate oxygen to your body’s tissue which can make you feel weak and tires (megaloblastic anaemia).
- low blood sugar (hypoglycaemia).

Side effects with unknown frequency:

- abnormalities in liver function tests or hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes).
- body produces high levels of blood acids called ketone (ketoacidosis).
- high levels of ketones (which occur when cells are broken down for energy) are present in the urine (ketonuria).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**Adverse drug reaction and quality problem reporting form**", found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/ and to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of DIAPHAGE.

5. How to store DIAPHAGE

- Store at or below 25 °C.
- Protect from light and moisture.

Store all medicines out of reach of children.

The blister should not be removed from the carton until required for use.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What DIAPHAGE contains

DIAPHAGE 500: each film coated tablet contains 500 mg metformin.

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The other ingredients are:

Tablet Core:

Colloidal anhydrous silica (Aerosil 200)

Magnesium stearate

Maize Starch

Povidone (PVP K-30)

Sodium starch glycollate (Primojel, Type A)

Film Coating:

Hypromellose (HPMCE-5)

Polyethylene glycol (Macrogol 6000)

Propylene glycol

Purified talc

Titanium dioxide (CI no. 77891).

What DIAPHAGE looks like and contents of the pack

DIAPHAGE 500: white-coloured, film-coated, round, biconvex tablets scored on one side and '500' embossed on the other side. 10 tablets per transparent/colourless PVC/aluminium blister packed in a carton. Each carton contains 9 blisters (90 tablets).

DIAPHAGE 850: white-coloured, film-coated, round, biconvex tablets plain on one side and '850' embossed on the other side. 10 tablets per transparent/colourless PVC/aluminium blister packed in a carton. Each carton contains 6 blisters (60 tablets).

DIAPHAGE 1000: white, capsule-shaped, binconvex, film-coated tablets having central breakline on one side and plain on the other side. 10 tablets per transparent/colourless PVC/aluminium blister packed in a carton. Each carton contains 6 blisters (60 tablets).

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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DIAPHAGE 500:

Namibia: NS2 16/21.2/0183

Botswana: S2 BOT1702932

DIAPHAGE 850:

Namibia: NS2 16/21.2/0184

Botswana: S2 BOT1402550

DIAPHAGE 1000:

Namibia: NS2 16/21.2/0185

Botswana: S2 BOT1402551

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.