Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. What DIAPRIDE PLUS 2 is and what it is used for
2. What you need to know before you take DIAPRIDE PLUS 2
3. How to take DIAPRIDE PLUS 2
4. Possible Side Effects
5. How to store DIAPRIDE PLUS 2
6. Contents of the pack and other information

1. What DIAPRIDE PLUS 2 is and what it is used for

Diapride Plus 2 is a medicine taken by mouth to help lower blood sugar

Diapride Plus 2 is used, with diet and physical exercise, to treat a certain form of diabetes (type 2 diabetes mellitus):

- In case the use of glimepiride or metformin alone does not control your blood glucose level,

- In place of taking the combination of glimepiride tablet with a metformin tablet.

2. What you need to know before you take DIAPRIDE PLUS 2

When you must not take it

Contraindications

Do not take DIAPRIDE PLUS 2 in the following cases:

- if you have insulin-dependent diabetes (type 1 diabetes requiring insulin therapy),

- if you have had serious problems with your diabetes in the past called diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue,

feeling sick (nausea), frequent urination and muscular stiffness),

- if you are allergic (hypersensitive) to glimepiride or metformin hydrochloride, or any of the other ingredients of Diapride Plus 2, to sulphonamides (medicines for bacterial infections such as sulfamethoxazole), other sulfonylureas (medicines used to lower your blood sugar such as glibenclamide) and Biguanides (medicines used to lower your blood sugar),

- if you are pregnant, planning to get pregnant or are breast-feeding,
- if you have or have had lactic acidosis (an increase in the amount of lactic acid in the body),
- if you have a kidney (renal) disease,
- if you have heart failure,
- if you have recently had a heart attack or any other heart problem, or have severe circulation problems or difficulty in breathing,
- if you have a liver (hepatic) disease,
- if you are a heavy drinker of alcohol,
- if you have a severe infection or are dehydrated,
- if you are going to have an X ray where you will be injected with dye,
- if you are not eating enough, if you are debilitated or if you suffer from particular hormone-induced

disorders (disorders of the pituitary or adrenal insufficiency).

Before you start to take it: Please follow closely the instructions for dosage, monitoring (blood and/or urine tests), diet and physical activity

(physical work and exercise) as discussed with your doctor.

Lactic acidosis: Lactic acidosis is an increase in the amount of lactic acid in the blood. It is a rare, but serious, side effect of metformin. This most often affects people who have severe kidney disease.

This drug should generally be avoided in patients with hepatic disease. You should be cautious against excessive

alcohol intake, either acute or chronic, when taking this drug, since alcohol potentiates the effects of metformin.

In addition, this drug should be temporarily discontinued prior to any intravascular radio-contrast study and

for any surgical procedure. Tell your doctor in these cases that you take Diapride Plus 2.

The symptoms of lactic acidosis include: rapid breathing, stomach pain, nausea, vomiting, and feeling cold.

If you experience some of these symptoms, stop taking Diapride Plus 2 and consult your doctor immediately.

Kidney function:

Your kidney function should be measured before starting the treatment and monitored regularly:

- At least once a year in patients with normal kidney function,
- At least two to four times a year in patients with kidney disease and in elderly subjects.

Inform your doctor that you are taking Diapride Plus 2 in the event of the following:

- Surgery, fever, infection, difficulty in eating
- Desire for pregnancy

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Your doctor may wish to change your dose of Diapride Plus 2 if you are taking other medicines, which may weaken or

strengthen the effect of Diapride Plus 2 on the level of sugar in your blood.

The following medicines can increase the blood sugar lowering effect of Diapride Plus 2. This can lead to a risk of hypoglycaemia (low blood sugar):

- Other medicinal products to treat diabetes mellitus (such as insulin or metformin)
- Medicinal products to treat pain and inflammation (phenylbutazone, azapropazone, oxyphenbutazone, aspirin-like medicines)
- Medicinal products to treat urinary infections (such as some long acting sulfonamides)
- Medicinal products to treat bacterial and fungal infections (tetracyclines, chloramphenicol, fluconazole, miconazole, quinolones, clarithromycin)
- Medicinal products to inhibit blood clotting (coumarin derivatives such as warfarin)
- Medicinal products supporting muscle build up (anabolics)
- Medicinal products used for male sex hormone replacement therapy
- Medicinal products to treat depression (fluoxetine, MAO inhibitors)
- Medicinal products lowering high cholesterol level (fibrates)
- Medicinal products lowering high blood pressure (ACE inhibitors)
- Medicinal products called antiarrhythmic agents used to control abnormal heart beat(disopyramide)
- Medicinal products to treat gout (allopurinol, Probenecid, sulfinpyrazone)
- Medicinal products to treat cancer (cyclophosphamide, ifosfamide, trofosfamide)
- Medicinal products used to reduce weight (fenfluramine)
- Medicinal product to increase circulation when given in a high dose intravenous infusion(pentoxifylline)
- Medicinal products to treat nasal allergies such as hay fever (tritoqualine)
- Medicinal products called sympatholytic to treat high blood pressure, heart failure, or prostate symptoms

The following medicines may decrease the blood sugar lowering effect of Diapride Plus 2. This can lead to a risk of hyperglycaemia (high blood sugar level):

- Medicinal products containing female sex hormones (oestrogens, progestogens)
- Medicinal products supporting urine production (thiazide diuretics)
- Medicinal products used to stimulate the thyroid gland (such as levothyroxine)
- Medicinal products to treat allergies and inflammation (glucocorticoids)
- Medicinal products to treat severe mental disorders (chlorpromazine and other phenothiazine derivatives)
- Medicinal products used to raise heart beat, to treat asthma or nasal congestion, coughs and colds, used to reduce weight, or used in life-threatening emergencies (adrenaline and sympathomimetics)
- Medicinal products to treat high cholesterol level (nicotinic acid)

- Medicinal products to treat constipation when they are used long term (laxatives)
- Medicinal products to treat seizures (phenytoin)
- Medicinal products to treat nervousness and sleep problems (barbiturates)
- Medicinal products to treat increased pressure in the eye (azetazolamide)
- Medicinal products to treat high blood pressure or lowering blood sugar (diazoxide)
- Medicinal products to treat infections, tuberculosis (rifampicin)
- Medicinal products to treat severe low blood sugar levels (glucagon)

The following medicinal products can increase or decrease the blood sugar lowering effect of Diapride Plus 2:

- Medicinal products to treat stomach ulcers (called H2 antagonists)
- Medicinal products to treat high blood pressure or heart failure such as beta-blockers, clonidine, guanethidine and reserpine. These can also hide the signs of hypoglycaemia, so special care is needed when taking these medicines

Diapride Plus 2 may either increase or weaken the effects of the following medicines:

- Medicinal products inhibiting blood clotting (coumarin derivatives such as warfarin)

Alcohol intake may increase or decrease the blood-sugar-lowering action of Diapride Plus 2in an unpredictably way. Alcohol intake increases the risk of lactic acidosis.

Lactic acidosis may occur when other medicines are given at the same time as Diapride Plus 2 such as: iodinated contrast materials and antibiotics having strong kidney toxicity (for example gentamicin).

3. How to take DIAPRIDE PLUS 2

Always take Diapride Plus 2 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take

The dose of Diapride Plus 2 depends on your needs, condition and results of blood and urine sugar tests and is

determined by your doctor. Do not take more tablets than your doctor has prescribed.

It is recommended to start the treatment with the lowest effective dose and your doctor might increase the dose depending on your blood glucose level.

When to take it

Diapride Plus 2 should be taken by mouth immediately before or with the meals. Swallow the tablets whole with about half a glass of water.

How long to take it

If you interrupt or stop the treatment you should be aware that the desired blood sugar lowering effect is not achieved or that the disease will deteriorate again. If you have any further questions on the use of this product ask your doctor or pharmacist.

If you forget to take Diapride Plus 2

Take your tablets with your next meal. Do not take a double dose to make up for a forgotten dose.

If you take too much (overdose)

If you happen to have taken too much Diapride Plus 2 or an additional dose there is a danger of hypoglycaemia and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice, and sweetened tea) and inform a doctor immediately. When treating hypoglycaemia due to accidental intake in children, the quantity of sugar given must be carefully controlled to avoid the possibility of producing dangerous hyperglycaemia. Persons in a state of unconsciousness must not be given food or drink.

Since the state of hypoglycaemia may last for some time it is very important that the patient is carefully monitored until there is no more danger. Admission into hospital may be necessary, also as a measure of precaution.

Severe cases of hypoglycaemia accompanied by loss of consciousness and coma are cases of medical emergency requiring immediate medical treatment and admission into hospital. It may be helpful to tell your family and friends to call a doctor immediately if this happens to you.

Because this medicine contains metformin, this may lead also to lactic acidosis. Please consult your doctor or pharmacist immediately.

While you are using DIAPRIDE PLUS 2

Things you must do

Important information about hypoglycaemia (low blood sugar)

When you take Diapride Plus 2, you may get hypoglycaemia (low blood sugar).

Please see below for additional information about hypoglycaemia, its signs and treatment.

Following factors could increase the risk of you getting hypoglycaemia:

- under nutrition, irregular meal time, or missed or delayed meal or period of fasting,
- increase of the amount of exercise you do and you don’t eat enough food or eat food containing less carbohydrate than usual,
- changes to your diet,
- consumption of alcohol, especially in combination with skipped meals,
- having kidneys that do not work properly,
- having severe liver disease,
- taking more Diapride Plus 2 than needed,
- certain uncompensated hormone induced disorders: disorders of thyroid glands and in anterior gland or adrenal cortex,
- taking certain other medicines If such risk factors for hypoglycaemia are present, it may be necessary to adjust the dosage of Diapride Plus 2, talk with your doctor or pharmacist. This also applies whenever illness occurs during therapy or any life-style changes.

The symptoms of hypoglycaemia may be milder or absent in those situations where hypoglycaemia develops gradually, in the elderly, and in patients with a certain type of nervous disease (autonomic neuropathy) or those

receiving treatment with other medications called beta-blockers, clonidine, reserpine, guanethidine, or other sympathicomimetics.

Treating hypoglycaemia: In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, sweetened tea.

You should therefore always take some form of sugar with you (e.g. sugar cubes). Remember that artificial sweeteners are not effective. Contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.

Laboratory Tests

The level of sugar in your blood or urine should be checked regularly.

Your doctor may also take blood tests to monitor your blood cell levels and liver function.

Things you must not do

Pregnancy and breast-feeding

You should not use Diapride Plus 2 if you are pregnant or planning to become pregnant or breast-feeding.

Things to be careful of

Driving and using machines

Your ability to concentrate or react may be reduced if your blood sugar is lowered (hypoglycaemia) or raised

(hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines).

Ask your doctor whether you can drive a car if you:

- have frequent episodes of hypoglycaemia,

- have fewer or no warning signals of hypoglycaemia

Important information about some of the ingredients of Diapride Plus 2

Diapride Plus 2 contains lactose. If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking this medicinal product.

4. Possible side EFFECTS 2

Like all medicines, Diapride Plus 2 can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms:

Hypoglycaemia:

Due to the blood-sugar-lowering action of Diapride Plus 2, hypoglycaemia may occur, and may last for some time. Signs of hypoglycaemia include:

- Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, problems sleeping, restlessness, aggression, problems with concentration, reduced alertness and reaction time, depression, confusion, problems with your speech and sight, slurred speech, shakiness, partial paralysis, dizziness, helplessness
- The following signs may also occur: sweating, clammy skin, anxiety, fast or increased heartbeat, high blood pressure, awareness of your heart beat, sudden strong pain in the breast that may radiate into neighbouring areas (angina pectoris and cardiac arrhythmias). If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop fits, lose self control, breathing may be shallow and your heart beat slowed down, you may fall into unconsciousness. The clinical picture of a severe reduced blood sugar level may resemble that of a stroke.

Lactic acidosis:

Some patients have experienced a condition called lactic acidosis (excess of lactic acid in your blood), particularly those kidneys are not working properly. Symptoms include: feeling cold or uncomfortable, severe nausea or vomiting, abdominal pain, unexplained weight loss, or rapid breathing. If you experience some of these symptoms, stop taking Diapride Plus 2 and consult a doctor immediately.

- Allergic reactions (including inflammation of blood vessels, often with skin rash) which may develop into serious reactions with difficulty in breathing, fall in blood pressure and sometimes progressing to shock.
- Abnormal liver function including yellowing of the skin and eyes (jaundice), problems with the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure.
- Allergy (hypersensitivity) of the skin such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions
- Digestive tract:

Feeling of being sick, diarrhoea, feeling full or bloated, and abdominal pain.

Eyes: Problems with your sight may occur when beginning treatment with Diapride Plus 2. This is due to changes in blood sugar levels and should soon improve.

Blood:

Decrease in the number of blood cells:

- Blood platelets (which increases risk of bleeding or bruising)
- White blood cells (which makes infections more likely)
- Red blood cells (which can make the skin pale and cause weakness or breathlessness).
- Low levels of vitamin B12 may be seen. Therefore if needed, monitor serum B12 levels.

Other undesirable effects:

- Taste of metal in your mouth.
- Decrease in the amount of sodium level in your blood.

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.

5. How to store DIAPRIDE PLUS 2

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Diapride Plus 2 contains

Active substance is Glimepiride & Metformin Hydrochloride

The other ingredients are: Hypromellose; Carmellose sodium; Dibasic calcium phosphate; Povidone; Colloidal anhydrous silica; Talc; Magnesium Stearate; Lactose; Ferric Oxide (RED); Sodium Starch Glycollate.

What Diapride Plus 2 looks like and contents of the pack

White/Brownish pink coloured, oblong shaped, uncoated, bi-layered sustained release tablets with '**MICRO**' engraved on both the sides.

Blister Pack of 10 tablets

Manufacturer

MICRO LABS LIMITED

92, Sipcot industrial complex

HOSUR-635 126, INDIA

Marketing Authorisation Holder

MICRO LABS LIMITED

31, Race course road

Bangalore-560001

INDIA

Date of Revision

Jan 2023