

## PATIENT INFORMATION LEAFLET

### 1. What is ILET B?

#### What is GLIMEPIRIDE?

Glimepiride is a medicine taken by mouth to help lower blood sugar. It belongs to a group of medicines called sulfonylureas. Glimepiride works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.

#### What Glimepiride is used for:

- Glimepiride is used to treat a certain form of diabetes (type 2 diabetes mellitus) when diet, physical exercise and weight reduction alone have not been able to control your blood sugar levels.

#### What is Metformin hydrochloride?

The name of this medicine is Metformin 500mg Tablets (called metformin in this leaflet). It belongs to a group of medicines called biguanides (a type of oral hypoglycaemic). Metformin is used for the sort of diabetes called Type 2 diabetes or non-insulin-dependent diabetes mellitus.

#### How metformin works

- In type 2 diabetes, there is too much sugar (glucose) in your blood. This is because your body does not make enough insulin or because it makes insulin that does not work properly.
- Insulin is a hormone that allows your body tissue to take glucose from the blood and use it for energy or for storage for future use.
- Metformin works by improving the sensitivity of your body to insulin. It helps your body to use glucose in the normal way again

#### Using this medicine

- This medicine is given when diet and exercise alone has not been able to control your blood sugar levels.
- Metformin can be given on its own. However, sometimes it is given with other medicines for diabetes or with insulin.
- In patients who are overweight, long-term use of metformin also helps to lower the risk of any problems related to diabetes

### 2. Before you take ILET B?

#### Before you take Glimepiride

Do not take Glimepiride and tell to your doctor if

- You are allergic (hypersensitive) to: Glimepiride or other sulfonylureas (medicines used to lower your blood sugar such as glibenclamide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the other ingredients of Glimepiride (listed in Section 6 What Glimepiride contains)

- You have insulin dependent diabetes (type 1 diabetes mellitus)

You have 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)

- You are in a diabetic coma
- You have severe kidney disease
- You have a severe liver disease

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Glimperide.

**Do not take Metformin if:**

- you are allergic (hypersensitive) to metformin or any of the other ingredients in this liquid (see section 6: Further information). An allergic reaction can include a rash, itching or shortness of breath.
- you have recently had a heart attack or any other heart problems
- you have severe circulation problems or difficulty in breathing
- you have liver or kidney problems
- you have had serious problems with your diabetes in the past called diabetic ketoacidosis. When you have this you lose weight quickly, feel sick (nausea) or are sick (vomiting). See also in Section 4: Possible side effects
- you have recently had a severe infection, injury or trauma (shock)
- you are dehydrated
- you are going to have an X-ray where you will be injected with a dye
- you are a heavy drinker of alcohol (more than 21 units a week for a man or 14 units a week for a woman). A unit is equivalent to a small glass of wine, one shot or half a pint of beer.
- you are pregnant, planning to get pregnant or are breast-feeding (see Pregnancy and Breast-feeding).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking metformin.

Take special care and check with your doctor or pharmacist before taking metformin if:

- You are elderly
- You are on a very low calorie diet (less than 1000 calories a day) or are fasting. This could increase the chances of you getting a very rare, but serious side effect called lactic acidosis (see section 4)

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

## **Operations and tests while taking metformin**

- The amount of sugar in your blood or urine should be checked regularly. Your doctor will also check your kidneys are working properly. This should be done at least once a year (more often if you are elderly or have kidney problems).
- If you are going to have an X-ray, tell your doctor you are taking metformin. If this involves having a dye injected, you must stop taking metformin.
- If you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking metformin before the operation. Your doctor may stop you taking metformin for a couple of days before and after the operation

## **Taking metformin with other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine. This includes medicines obtained without a prescription, including herbal medicines. This is because metformin can affect the way some other medicines work. Also, some medicines can affect the way metformin works. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for high blood pressure (hypertension) such as water tablets (diuretics), ACE inhibitors (such as enalapril)
- Medicines for asthma such as salbutamol or formoterol (beta-2-agonists)
- Medicines used for inflammation called steroids If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking metformin.

## **Taking metformin with food and drink**

- You need to eat carbohydrates regularly throughout the day. If your doctor has given you advice on your diet, you need to continue to follow this.
- Do not drink large amounts of alcohol or take medicines containing alcohol while taking metformin

## **Pregnancy and breast-feeding**

Do not take this medicine and talk to your doctor if you are pregnant, planning to get pregnant or are breast-feeding

- Metformin on its own does not usually affect your ability to drive.
- However, if you also take other medicines which lower blood sugar you may feel faint, dizzy, weak or shaky. If this happens, do not drive or use any tools or machines.

### **3. How to take ILET B ?**

#### **How to take Glimpiride**

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

- Take this medicine by mouth, just before or with the first main meal of the day (usually breakfast). If you do not have breakfast you should take the product on schedule as prescribed by your doctor. It is important not to leave out any meal when you are on Glimpiride

- Swallow the tablets whole with at least half glass of water. Do not crush or chew the tablets. How much to take: The dose of Glimpiride 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.

- The usual starting dose is one Glimpiride 1 mg tablet once a day

- If necessary, your doctor may increase the dose after each 1 - 2 weeks of treatment

- The maximum recommended dose is 6 mg Glimpiride per day

- A combination therapy of glimpiride plus metformin or of glimpiride plus insulin may be started. In such a case your doctor will determine the proper doses of glimpiride, metformin or insulin individually for you

- Your dose of Glimpiride may need to be adjusted if you change weight, change your lifestyle, or if you are under a lot of stress. Please speak to your doctor if any of these situations apply to you.

#### **If you take more Glimpiride than you should**

If you happen to have taken too much Glimpiride or an additional dose there is a danger of hypoglycaemia (signs of hypoglycaemia see Section 2 - Take special care with Glimpiride) and therefore you should instantly consume enough sugar (e.g. a small bar of sugar cubes, sweet juice, 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. Show the doctor the package or remaining tablets, so the doctor knows what has been taken. 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.

#### **If you forget to take Glimpiride**

If you forget to take a dose, do not take a double dose to make up for forgotten doses.

## **If you stop taking**

Glimepiride 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 get worse again. Keep taking Glimepiride until your doctor tells you to stop.

## **How to take metformin hydrochloride**

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

Taking this medicine

- Swallow the tablets whole with a glass of water.
- Do not crush or chew the tablets.
- Take metformin with or after food. This lowers the chance of getting an upset stomach.
- Try to take your medicine at the same time each day so that it becomes part of your daily routine.
- Keep taking metformin until your doctor tells you to stop. Do not stop taking metformin just because you feel better. If you stop your illness may get worse.

How much to take Adults

- The usual starting dose is one tablet 2 or 3 times a day. Your doctor will tell you when to take this
- After 10 to 15 days, your doctor may slowly increase your dose until the right dose for you is reached. This will help lower the chances of getting side effects such as feeling sick (nausea) or being sick (vomiting).
- The maximum daily dose is six 500mg tablets

## **Elderly**

- Your doctor may give you a much lower starting dose as there is a risk of kidney problems.

## **Teenagers and children aged 10 years or older**

- The usual starting dose is one tablet each day. Your doctor will tell you when to take this
- After 10 to 15 days, your doctor may slowly increase your dose until the right dose is reached. This will help lower the chances of getting side effects such as feeling sick (nausea) or being sick (vomiting).
- The maximum daily dose is four 500mg tablets.

## **Children aged under 10 years**

Metformin is not recommended for use in children under 10 years old.

Taking metformin with insulin

- If your doctor wants you to take metformin with insulin the usual starting dose of metformin is one tablet 2 or 3 times a day.
- The insulin dose will change depending on your blood sugar level If you take more metformin than you should If you take too many tablets tell your doctor or go to the nearest hospital casualty department straight away.

Remember to take the pack and any remaining tablets with you. This is so the doctor knows what you have taken. The following effects may happen if you take too much metformin: unexpected weight loss, feeling very sick or being very sick, very fast breathing which you cannot stop, stomach pains or feeling cold. You may have something called lactic acidosis. The doctor may use a method called 'haemodialysis' to remove the extra lactate and metformin from your body.

#### **If you forget to take metformin**

- If you forget to take a dose, take it as soon as you remember, with your next meal. However, if it is time for your next dose, do not take the missed dose. Take only a single dose as usual.
- Do not take a double dose to make up for a forgotten dose

#### **If you stop taking metformin**

Keep taking this medicine until your doctor tells you to stop. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

#### **For Glimepiride:**

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

- 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
- Severe hypoglycaemia including loss of consciousness, seizures or coma. Some patients experienced the following side effects whilst taking Glimepiride:  
Rare side effects (affects 1 to 10 patients in 10,000)
  - Lower blood sugar than normal (hypoglycaemia) (See Section 2 - Take special care with Glimepiride)
  - 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). These problems generally get better after you stop taking Glimepiride.
- Very rare side effects (affects less than 1 patient in 10,000)
  - 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. If you experience any of these symptoms, tell your doctor immediately

- Abnormal liver function including yellowing of the skin and eyes (jaundice), impairment of the bile flow (cholestasis), inflammation of the liver (hepatitis) or liver failure. If you experience any of these symptoms, tell your doctor immediately

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

- Decrease in the amount of sodium level in your blood (shown by blood tests)

**Other side effects include:**

- Allergy (hypersensitivity) of the skin may occur such as itching, rash, hives and increased sensitivity to sun. Some mild allergic reactions may develop into serious reactions with swallowing or breathing problems, swelling of your lips, throat or tongue. Therefore in the event of one of these side effects, tell your doctor immediately

- Allergic reactions with sulfonylureas, sulfonamides, or related drugs may occur

- Problems with your sight may occur when beginning treatment with Glimepiride. This is due to changes in blood sugar levels and should soon improve

- Increased liver enzymes

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.

**For Metformin:**

Like all medicines metformin can cause side effects, although not everybody gets them. Stop taking metformin and see a doctor or go to a hospital straight away if you get any of the following very rare side effects:

- unexpected weight loss

- feeling very sick (nausea) or being very sick (vomiting)

- very fast breathing which you cannot stop

- stomach pains or feeling cold This may mean you have something called “diabetic ketoacidosis” or “lactic acidosis”. These can be signs of serious problems with your diabetes. If this happens, see a doctor as you will need treatment straight away.

Other side effects:

Very common (affects more than 1 in 10 people)

- Stomach problems such as feeling sick (nausea), being sick (vomiting), diarrhoea, stomach pain and loss of appetite. These side effects are most likely to happen at the start of treatment.

- They usually last for a short time. It helps to take the dose with or after a meal.

Common (affects less than 1 in 10 people)

- taste of metal in your mouth Very rare (affects less than 1 in 10,000 people)

- skin rash (including redness, itching, hives).
- low levels of vitamin B12. Over time this may lead to anaemia, a sore mouth or tongue or possibly numbness or tingling in the limbs.
- liver problems, abnormal liver function tests and hepatitis (inflammation of the liver) that may result in jaundice. If you notice yellowing of the eyes/skin contact your doctor immediately.

### **5.How to store ILET B**

Store below 30°C. Protect from light and moisture

### **6.Further information:**

Each bilayered uncoated tablets contains :

Metformin hydrochloride USP 500 mg

Glimepiride USP 1 mg / 2 mg

Colors:Iron oxide red

### **What ILET B Tablets look like and contents of the pack**

10 tablets of ILET B (Glimepiride 1/2 mg and Metformin hydrochloride 500 mg ER Tablets) are sealed with plain aluminium foil on one side and PVC foil on the other side in the form a blister pack and 3 such blister packs are further packed in a printed outer carton along with instructions for use.

### **Manufacturer:**

Name	:	<b>MSN LABORATORIES PRIVATE LIMITED</b> (Formulations Division)
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