

## **Package leaflet: Information for the user**

### **Metformin Orifarm 500 mg, 850 mg and 1000 mg film-coated tablets**

metformin hydrochloride

**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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their sign of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Metformin Orifarm are and what they are used for**

Metformin Orifarm contain the active ingredient metformin hydrochloride. Metformin hydrochloride belongs to a group of medicines called biguanides used for the treatment of non-insulin-dependent diabetes mellitus (type 2 diabetes) in adults and children from 10 years of age.

Insulin is a hormone produced by the pancreas that makes your body take in glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.

If you have diabetes, your pancreas does not make enough insulin or your body is not able to use properly the insulin it produces. This leads to a high level of glucose in your blood. Metformin helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking Metformin tablets over a long period of time also helps to lower the risk of complications associated with diabetes. Metformin tablets are associated with either a stable body weight or modest weight loss.

Metformin Orifarm are a medicine used to lower high blood sugar levels in patients with diabetes mellitus (type 2 diabetes); particularly in overweight patients when dietary management and exercise alone does not result in control of blood sugar.

#### **Adults**

Your doctor can prescribe Metformin Orifarm on their own (monotherapy) or in combination with other oral antidiabetic agents, or with insulin.

#### **Children and adolescents**

For children from 10 years of age and for adolescents the doctor can prescribe Metformin Orifarm alone (monotherapy) or in combination with insulin.

## 2. What you need to know before you take Metformin Orifarm

### Do not take Metformin Orifarm

- if you are allergic to metformin hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if 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.
- if you have severely reduced kidney function.
- if your kidney function worsens as a consequence of e.g.
  - loss of too much water (dehydration) due to long-lasting vomiting or severe diarrhoea. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see „Warnings and precautions“ below)
- If you have a severe infection, such as infection affecting your lung or bronchial system or your kidney. Severe infection may lead to kidney problems, which can put you at risk for lactic acidosis.(see „Warnings and precautions“ below)
- if you have acute or chronic diseases which may lead to reduced amount of oxygen in body tissues (tissue hypoxia) such as
  - heart failure, or difficulties breathing
  - recent heart attack (myocardial infarction)
  - collapse or trauma (shock)
- if you have liver problems, drink a lot of alcohol or suffer from alcoholism.

Make sure you ask your doctor for advice, if

- you need to have an examination such as X-ray or scan involving the injection of contrast medicines that contain iodine into your bloodstream
- you need to have major surgery.

You must stop taking metformin for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instruction precisely.

### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Metformin Orifarm .

#### Risk of lactic acidosis

Metformin Orifarm 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 Metformin Orifarm 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 Metformin Orifarm 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.

Talk to your doctor promptly for further instructions if:

- You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
- You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

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

Metformin Orifarm on its own do not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin Orifarm together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides), there is a risk of hypoglycaemia. If you experience symptoms of hypoglycaemia such as weakness, dizziness, increased sweating, fast heart beating, vision disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

During treatment with Metformin Orifarm, 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.

### **Other medicines and Metformin Orifarm**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

If you need to have an injection of contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Metformin Orifarm before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Metformin Orifarm.

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

- corticosteroids (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)
- medicines which increase urine production (diuretics)
- 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)
- specific medicines for the treatment of bronchial asthma ( $\beta$ 2-agonists, e.g. salbutamol)
- medicines that may change the amount of Metformin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib)
- other medicines used to treat diabetes.

### **Metformin Orifarm with alcohol**

Avoid excessive alcohol intake while taking Metformin Orifarm since this may increase the risk of lactic acidosis (see section “Warnings and precautions”).

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Diabetic women who are pregnant or planning to become pregnant, should not be treated with Metformin tablets. Instead, insulin should be used to maintain blood glucose levels as close to normal as possible. Inform your doctor if you are pregnant or thinking of becoming pregnant so that he or she can change you to insulin therapy.

This medicinal product should not be used while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Taking metformin alone (monotherapy) does not cause low blood sugar levels (hypoglycaemia) and therefore has no effect on your ability to drive or use machines.

Taking metformin in combination with other antidiabetic agents (e.g. sulphonylureas, Insulin or meglitinides) may cause low blood sugar levels (with symptoms, such as sweating, fainting, dizziness or weakness) and thus affecting your ability to drive and use machines or work safely. Symptoms of hypoglycaemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

## **3. How to take Metformin Orifarm**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Metformin Orifarm cannot replace the benefits of a healthy lifestyle. Continue to follow any advice about diet that your doctor has given you and get some regular exercise.

The dose of Metformin Orifarm should be determined by the doctor according to your blood sugar levels.

Unless prescribed differently by your doctor, the recommended dose is:

#### Dosage for adults

The usual starting dose is 500 mg or 850 mg metformin hydrochloride 2-3 times a day. The maximum daily dose is 3000 mg metformin hydrochloride, taken as 3 divided doses.

#### Dosage for children from 10 years of age and adolescents:

The usual starting dose is 500 mg or 850 mg metformin hydrochloride once a day. The dosage can be increased up to the maximum recommended daily dose of 2000 mg metformin hydrochloride per day, taken as 2 or 3 divided doses. Treatment of children 10-12 years of age is only recommended on specific advice from your doctor, as experience in this age group is limited.

#### If you have reduced kidney function

Your doctor may prescribe a lower dose.

#### If you are elderly

Your dose may be adjusted if you are elderly.

#### If you take insulin too

Your doctor will tell you how to start Metformin tablets.

### **Monitoring**

- Your doctor will adapt your dose of Metformin to your blood glucose levels. Make sure that you talk to your doctor regularly. This is particularly important for children and adolescents or if you are an older person.
- Your doctor will also check at least once a year how well your kidneys work. You may need more frequent checks if you are an older person or if your kidneys are not working normally.

### **How to take Metformin Orifarm**

Take Metformin tablets with or after a meal. This will avoid you having side effects affecting your digestion.

Do not crush or chew the tablets. Swallow each tablet with a glass of water.

- If you take one dose a day, take it in the morning (breakfast).
- If you take two divided doses a day, take them in the morning (breakfast) and evening (dinner).
- If you take three divided doses a day, take them in the morning (breakfast), at noon (lunch) and evening (dinner).

850 mg: The scoreline is only there to help you break the tablet if you have difficulty swallowing it whole.

1000 mg: The tablet can be divided into equal doses.

If, after some time, you think that the effect of Metformin Orifarm is too strong or too weak, talk to your doctor or pharmacist.

### **If you take more Metformin Orifarm than you should**

Inform your doctor immediately if you have taken more tablets than you should have.

An overdose of Metformin Orifarm does not lead to hypoglycaemia but increases the risk of hyperacidity of the blood caused by lactic acid (lactic acidosis). Symptoms of early hyperacidity are similar to the side effects of metformin on the gastrointestinal tract: sickness, vomiting, diarrhoea and abdominal pain. In severe cases you could also get muscle pain and muscle cramps, very fast breathing which you cannot stop, as well as a clouding of consciousness and coma. This may develop within hours and requires immediate emergency treatment in a hospital.

### **If you forget to take Metformin Orifarm**

If you forget to take Metformin Orifarm, take the prescribed amount of Metformin Orifarm at the next prescribed time and try to keep to the prescription in future. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Metformin Orifarm**

If you stop treatment with Metformin Orifarm you have to be aware of the risk of uncontrolled blood sugar and of the long-term effects of diabetes mellitus such as damage on eyes, kidneys and blood vessels.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur:

Metformin Orifarm may cause a very rare (may affect up to 1 user in 10,000), but very serious side effect called lactic acidosis (see section “Warnings and precautions”). If this happens you must **stop**

**taking Metformin Orifarm and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

*Very common side effects (may affect more than 1 in 10 people)*

- Digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of appetite. These side effects most often happen at the beginning of the treatment with Metformin Orifarm . It helps if you spread the doses over the day and if you take Metformin Orifarm with or straight after a meal. **If symptoms continue, stop taking Metformin Orifarm and talk to your doctor.**

*Common side effects (may affect up to 1 in 10 people)*

- Changes in taste.
- Decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

*Very rare side effects (may affect up to 1 in 10,000 people)*

- Lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. Symptoms of lactic acidosis are non-specific (see section „Warning and precautions“)
- 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). If this happens to you, **stop taking Metformin Orifarm and talk to your doctor.**
- Skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

### **Children and adolescents**

Limited data in children and adolescents showed that adverse events were similar in nature and severity to those reported in adults.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. By reporting the side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Metformin Orifarm**

Keep this medicine out of the sight and reach of children. If a child is treated with Metformin, parents and caregivers are advised to oversee how this medicine is used.

Do not use this medicine after the expiry date which is stated on the blister, bottle or carton after "EXP". The expiry date refers to the last day of that month.

### **Storage conditions**

This medicine does not require any special storage conditions.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Metformin Orifarm contains**

- The active substance is metformin hydrochloride. Each tablet contains 500 mg, 850 mg or 1000 mg metformin hydrochloride equivalent to 390 mg, 663 mg or 780 mg of metformin respectively.
- The other ingredients are: sodium starch glycolate (Type A), povidone K-30, maize starch, colloidal anhydrous, silica, magnesium stearate, hypromellose 15cP, talc, titanium dioxide (E 171), macrogol 6000, propylene glycol.

#### **What Metformin tablets looks like and contents of the pack**

500 mg: White to off-white round, biconvex, film-coated tablets which are plain on both sides.

850 mg: White to off-white capsule shaped, biconvex, film-coated tablets with scoreline on one side and plain on the other side.

1000 mg: White to off-white oval shaped, biconvex, film-coated tablets, with a deep scoreline on one side and scoreline on the other side.

Blister: 100x1, 9, 10, 20, 21, 30, 40, 50, 56, 60, 84, 90, 100, 120, 180, 200, 300, 500, 600 or 1000 tablets

Plastic bottle: 10, 20, 21, 30, 40, 50, 56, 60, 90, 100, 120, 180, 200, 300, 400, 500, 600 or 1000 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturers**

<To be completed nationally>

#### **This medicinal product is authorised in the Member States of the EEA under the following names**

Sweden, Denmark and Norway: Metformin Orifarm

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