

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

### **Metophage 500 mg Film-Coated Tablets**

### **Metophage 850 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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 Metophage is and what it is used for
2. What you need to know before you take Metophage
3. How to take Metophage
4. Possible side effects
5. How to store Metophage
6. Contents of the pack and other information

#### **1. What Metophage is and what it is used for**

Metophage contains metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

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. Metophage helps to lower your blood glucose to as normal a level as possible.

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

Metophage is used to treat patients with type 2 diabetes (also called 'non-insulin dependent diabetes') when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.

**Adults** can take Metophage on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).

**Children** 10 years and over and adolescents can take Metophage on its own or together with insulin.

#### **2. What you need to know before you take Metophage**

##### **Do not take Metophage:**

- if you are **allergic** to metformin or any of the other ingredients of this medicine (listed in section 6)
- if you have severely reduced kidney function
- 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 **liver problems**
- if you drink a lot of **alcohol**
- if you **lost too much water** from your body (dehydration), such as due to long-lasting or severe diarrhoea, or if you have vomited several times in a row. 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 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' below).
- if you are treated for acute heart failure or have recently had a heart attack, have severe problems with your circulation (such as shock) or have 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” below).

If any of the above applies to you, talk to your doctor, before you start taking this medicine.

**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 Metophage 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 instructions precisely.

**Warnings and precautions**

**Risk of lactic acidosis**

Metophage 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 Metophage 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 Metophage 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.

Metophage on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metophage 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.

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

During treatment with Metophage, 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 Metophage**

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dose of Metophage. 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)
- beta-2 agonists such as salbutamol or terbutaline (used to treat 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)
- medicines that may change the amount of Metophage in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib)
- **medicines to lower blood sugar levels** such as insulin or those taken orally  
Taking these medicines together with Metophage could cause your blood sugar levels to become too low. See under “Warnings and precautions”.

### **Metophage with alcohol**

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

### **Pregnancy and breast-feeding**

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.

- **Pregnancy**  
If you are pregnant or wish to become pregnant you should **not take Metophage**. Please inform your doctor if this applies as metformin should be interrupted and replaced with insulin treatment.
- **Breast-feeding**  
Do **not take Metophage** without first talking to your doctor if you are breast-feeding.

### **Driving and using machines**

Metophage on its own does not cause hypoglycaemia (a blood glucose level which is too low). This means that it will not affect your ability to drive or use machines. However, take special care if you take Metophage together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulphonylureas, insulin, meglitinides). 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 Metophage**

## Metophage 500 mg:

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you have reduced kidney function, your doctor may prescribe a lower dose.

Metophage 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.

### **Adults:**

- The recommended starting dose is: 1 Metophage tablet 2 to 3 times daily.
- After taking Metophage for about 2 weeks your doctor may measure your blood sugar and adjust the dose.
- Maximum dose: 6 Metophage tablets\* daily, divided into 3 doses.

### **Children 10 years and over**

- Usual starting dose: is 1 Metophage tablet or 850 mg\* metformin hydrochloride daily.
- After the child has taken Metophage for about 2 weeks, the doctor may measure the blood sugar and adjust the dose.
- Maximum dose: 4 Metophage tablets\* daily, divided into 2 or 3 doses.

\* Tablets containing 850 mg and 1000 mg active substance metformin hydrochloride are also available, for individual dose adjustment.

### **Patients 65 years and over**

The doctor determines the Metophage dose based on your kidney function, as kidney impairment occurrence is high in this group. See also section 2 under “Warnings and precautions”.

## Metophage 850 mg:

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you have reduced kidney function, your doctor may prescribe a lower dose.

### **Adults:**

- Usual dose: 1 Metophage tablet 2 to 3 times daily
- After taking Metophage for about 2 weeks your doctor may measure your blood sugar and adjust the dose.
- Maximum dose: 3000 mg\* metformin hydrochloride daily, divided into 3 doses.

### **Children 10 years and over**

- Usual starting dose: 500 mg\* metformin hydrochloride or 1 Metophage tablet daily.
- After the child has taken Metophage for about 2 weeks, the doctor may measure the blood sugar and adjust the dose.
- Maximum dose: 2000 mg\* metformin hydrochloride daily, divided into 2 or 3 doses.

\* Tablets containing 500 mg and 1000 mg active substance metformin hydrochloride are also available, for individual dose adjustment.

### **Patients 65 years and over:**

The doctor determines the Metophage dose based on your kidney function, as kidney impairment occurrence is high in this group.

See also section 2 under “Warnings and precautions”.

### **Method of use**

Swallow the tablets whole and with a glass of water **with or after meals**.

### **Monitoring**

- Your doctor will perform regular blood glucose tests and will adapt your dose of Metophage 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 elderly.
- Your doctor will also check at least once a year how well your kidneys work. You may need more frequent checks if you are elderly or if your kidneys are not working normally.

### **Duration of use**

To be decided by your attending doctor.

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

If you have taken too much Metophage, contact your doctor or the nearest hospital immediately.

A Metophage overdose will not cause excessively low blood sugar levels. However, it increases the risk of over-acidification with lactic acid in the blood with lactic acid.

Over-acidification symptoms are listed at the end of sub-chapter “Do not take Metophage”. Muscle pain with cramps, deep and rapid breathing, loss of consciousness and coma can develop within hours. This requires immediate emergency admission to hospital.

### **If you forget to take Metophage**

If you forget to take a dose, skip that dose and take your next dose at the next prescribed time.

Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Metophage**

Stopping Metophage treatment without your doctor’s consent can cause your blood sugar level to rise uncontrollably. This will increase the risk of long term damage occurring e.g. to the eyes, kidney and vessels.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Metophage may cause a very rare (may affect up to 1 in 10,000 people), but very serious side effect called lactic acidosis (see section “Warnings and precautions”). If this happens you must **stop taking Metophage and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Other possible side effects

**Very common**, may affect more than 1 in 10 people.

- nausea
- vomiting
- diarrhoea
- abdominal pain
- loss of appetite.

These complaints mainly occur when beginning therapy and spontaneously disappear in most cases. To prevent these complaints take the tablets with or after meals and in 2 to 3 doses daily.

**Common**, may affect up to 1 in 10 people

- change in taste.

**Very rare**, may affect up to 1 in 10,000 people

- reduction in the vitamin B<sub>12</sub> uptake in the intestine when treated for a long-term period with Metophage
  - skin reddening
  - itching
  - itchy rash
  - abnormalities in liver function tests or liver inflammation; this may cause:
    - tiredness
    - loss of appetite
    - weight loss
    - yellowing of the skin or whites of the eyes.
- Stop taking Metophage and tell your doctor straight away if this occurs.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Metophage**

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special storage conditions.

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

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

### **What Metophage contains**

The active substance is metformin hydrochloride.

Each film-coated tablet contains 500 mg metformin hydrochloride equivalent to 390 mg of metformin base.

Each film-coated tablet contains 850 mg metformin hydrochloride equivalent to 662.9 mg of metformin base.

The other ingredients are: Povidone K90, magnesium stearate, hypromellose, macrogol 4000, titanium dioxide (E171).

### **What Metophage looks like and contents of the pack**

#### *Metophage 500 mg Film-Coated Tablets*

Round, white, double radius film-coated tablet, embossed "M 500" on one side and plain on the reverse side.

The tablets are packed in PVC/aluminium blisters and inserted in a carton or packed in a HDPE tablet container with LDPE caps or with PP caps and desiccant canister.

Pack sizes:

HDPE tablet container: 30, 60, 90, 100, 250, 400 film-coated tablets.

Blister: 30, 50, 60, 84, 90, 100, 250 film-coated tablets.

#### *Metophage 850 mg Film-Coated Tablets*

White, oval film-coated tablet with a score on one side and embossed "M 850" on the other side.

The tablets are packed in PVC/aluminium blisters and inserted in a carton or packed in a HDPE tablet container with LDPE caps or with PP caps and desiccant canister.

Pack sizes:

HDPE tablet container: 30, 100, 200, 250 film-coated tablets.

Blister: 30, 40, 56, 60, 90, 100, 250 film-coated tablets.

Keep the desiccant canister in the bottle.

Not all pack sizes may be marketed.

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

##### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

##### **Manufacturers**

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek S.A., ul. Domaniewska 50C, 02-672 Warszawa, Poland.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

LEK S.A., Ul. Podlipie 16, 95 010 Stryków, Poland.

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

IE: Metophage 500 mg Film-Coated Tablets

IT: METFORMINA HEXAL AG

NL: METFORMINE HCL SANDOZ TABLET 500 MG, filmomhulde tabletten

IE: Metophage 850 mg Film-Coated Tablets

IT: METFORMINA HEXAL AG

NL: METFORMINE HCL SANDOZ TABLET 850 MG, filmomhulde tabletten

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