Package leaflet: Information for the user

Metophage 500 mg film-coated tablets
Metophage 850 mg film-coated tablets

Metformin hydrochloride

ROWEX®

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 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

Metophage is used to treat people with **type 2 diabetes**, when diet and exercise alone cannot sufficiently control the blood sugar levels. Type 2 diabetes is where insulin production and/or its effects are gradually reduced. Metophage is used particularly in overweight patients.

Adults can use Metophage on its own or together with other medicines to treat diabetes taken by mouth, or insulin.
Children 10 years and over can use Metophage on its own or together with insulin.

Metophage belongs to a group of medicines called biguanides, which lower blood sugar levels. It also helps reduce the risk of complications associated with diabetes in overweight adults.

2 What you need to know before you take Metophage

Do not take Metophage
and inform your doctor if you are/have:
- **allergic** (hypersensitive) to metformin or any of the other ingredients of this medicine (listed in section 6)
- **severe diabetes** combined **with** a condition of **too much acid in the blood** called ketoacidosis, due to insulin lack. Symptoms of this condition are:
  - stomach pain
  - fast and deep breathing
  - sleepiness or unusual fruity odour to breath
  - rapid weight loss

  This can lead to the preliminary stage of coma.
- **severe diabetes** combined **with onset of loss of consciousness** called diabetic precoma due to blood acidification
- **kidney problems**
- **liver problems**
- regularly drink large amounts of **alcohol**
- **dehydrated**, such as after
  - ongoing or severe diarrhoea, or
  - continuous vomiting.
- treated for **heart failure**
- recently had a **heart attack**
- severe **problems** with your **circulation**
- **breathing** difficulties
- **severe infection**, such as that affecting the lung, lung airways or kidney

Stop taking Metophage and inform your doctor immediately if a serious condition called **lactic acidosis** occurs during therapy. This will particularly affect you if you have reduced kidney function.
Symptoms are:
- vomiting
- abdominal pain with muscle cramps
- generally feeling very tired and unwell
- difficulty breathing

Urgent hospital treatment is required to prevent coma onset. Other illnesses, prolonged fasting, poor blood control or alcohol intake can increase the risk of this severe disorder occurring.

Warnings and precautions
Ask your doctor for advice before taking Metophage if any of the following conditions apply to you:
- undergoing **surgery** under general anaesthetic
  Your doctor will **stop Metophage treatment** 48 hours before. If he decides your kidney function is normal, you can continue taking Metophage 48 hours after the surgery. It is important that you follow your doctor's instructions precisely.
  Your doctor will decide if you need any other treatment during this time.
- symptoms of **blood sugar levels below normal** are:
  - weakness
  - dizziness
  - increased sweating
  - rapid heartbeat
  - vision disorders
  - difficulty concentrating

  Eat or drink something containing sugar if this occurs. Metophage alone cannot cause blood sugar levels to decrease too much, however other medicines for diabetes can.
- **overweight**
  Maintain your calorie controlled diet.
- **using other medicines**
  See "Other medicines and Metophage".

It is important to do the following regularly:
- consult your prescribing doctor particularly at the beginning of Metophage treatment
- usual blood and urine laboratory tests to manage your diabetes
- **kidney function checks** by your doctor at least once a year
  People 65 years or older and people **just within normal kidney function** need these checks at least two to four times a year.
- eat meals regularly throughout the day when using Metophage – See also section 3 under "Method of use".

Children under 10 years
Metophage is **not recommended** for this age group.

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

The following medicines can influence or be influenced by Metophage
- **iodinated contrast agents**
  Your doctor will **stop Metophage therapy** before an X-ray examination if these contrast media are used. If he decides your kidney function is normal, you can continue taking Metophage 48 hours after the examination. Your doctor will decide if you need any other treatment during this time.
- **alcohol** containing medicines
- **glucocorticoids**, medicines to prevent organ transplant rejection, reduce inflammation such as of the skin or for asthma
- **medicines, which expand the airways**, such as salbutamol, fenoterol and terbutaline
- If there is a **risk of reduced kidney function**, your doctor must take particular care administering Metophage. This applies for example when you are treated with:
  - **medicines to treat high blood pressure**
  - **water pills**
  - certain **medicines to treat pain, fever and inflammation**

  Reduced kidney function more commonly occurs in elderly patients.
- medicines to treat high blood pressure, with **active substance names ending** in "-pril"
- **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
Alcohol increases the risk of the side effect lactic acidosis. It is therefore advisable that you refrain from consuming alcohol.

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 Metophage 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
- When Metophage alone is used to treat diabetes it does not influence the ability to drive or use machines.
- If you use other medicines to treat diabetes in addition to Metophage, your blood sugar level can become too low. This could reduce your ability to drive or use machines. Discuss this with your doctor before driving or operating machinery.

3 How to take Metophage

Metophage 500 mg Film-Coated Tablets:

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

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

continued on the next page >>

Pharmacode
Pharmacode
Pharmacode
Pharmacode

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.

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 Film-Coated Tablets:

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

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

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.

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**.

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 efffects

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

Stop taking Metophage immediately and tell your doctor straight away if you have the following signs of lactic acidosis:
- vomiting
- abdominal pain with muscle cramps
- generally feeling very tired and unwell
- difficulty in breathing
- body temperature below normal
- coma

See chapter 2, under "Warnings and precautions".

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 of 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_{12} 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.imb.ie;
e-mail: imbpharmacovigilance@imb.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Metophage

Keep out of the sight and reach of children.

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

This medicinal product 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.
  Metophage 500 mg
  Each film-coated tablet contains 500 mg metformin hydrochloride equivalent to 390 mg of metformin base
  Metophage 850 mg
  Each film-coated tablet contains 850 mg metformin hydrochloride equivalent to 662.9 mg of metformin base
- The other ingredients are:
  Tablet core:
  Povidone K 90, magnesium stearate.

  Film coating:
  hypromellose, macrogol 4000, titanium dioxide.

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.

Metophage 500 mg Film-Coated Tablets are available in
- HDPE tablet container with LDPE caps with 30, 60, 90, 100, 250, 400 film-coated tablets
- PVC aluminium blisters with 30, 50, 60, 84, 90, 100, 250 film-coated tablets.

Not all pack sizes may be marketed.

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.
Metophage 850 mg Film-Coated Tablets are available in
- HDPE tablet container with LDPE caps with 30, 100, 200, 250 film-coated tablets
- PVC aluminium blisters with 30, 40, 56, 60, 100, 250, film-coated tablets.

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.
Salutas Pharma GmbH, Dieselstrasse 5, 70839 Gerlingen, 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 Strykow, Poland.

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

IE: Metophage 500 mg Film-Coated Tablets
Metophage 850 mg Film-Coated Tablets
IT: METFORMINA HEXAL AG 500 mg compresse rivestite con film
METFORMINA HEXAL AG 850 mg compresse rivestite con film
NL: Metformine HCl Sandoz tablet 500 mg
Metformine HCl Sandoz tablet 850 mg

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