

<b>Sandoz</b>	Business use only	Page 1 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **METFORMIN 500 mg film-coated tablets** **METFORMIN 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. 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 side effects not listed in this leaflet .

#### **In this leaflet:**

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

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

Metformin 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. **Metformin** is used particularly in overweight patients.

**Adults** can use **Metformin** on its own or together with other medicines to treat diabetes taken by mouth, or insulin.

**Children** 10 years and over can use **Metformin** on its own or together with insulin.

**Metformin** 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 METFORMIN**

##### **Do not take METFORMIN**

and inform your doctor if you are/have:

- **allergic** (hypersensitive) to metformin or any of the other ingredients of **Metformin**
- **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.

<b>Sandoz</b>	Business use only	Page 2 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

- **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 METFORMIN 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 **Metformin** if any of the following conditions apply to you:

- undergoing **surgery** under general anaesthetic  
Your doctor will **stop Metformin treatment** 48 hours before. If he decides your kidney function is normal, you can continue taking **Metformin** 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. **Metformin** 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 "Using other medicines".

It is important to do the following regularly:

- consult your prescribing doctor particularly at the beginning of **Metformin** treatment
- usual blood and urine laboratory tests to manage your diabetes
- **kidney function checks** by your doctor at least once a year

<b>Sandoz</b>	Business use only	Page 3 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

**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 **Metformin** – See also section 3 under “Method of use”.

### **Children under 10 years**

**Metformin** is **not recommended** for this age group.

### **Other medicines and METFORMIN**

**Tell your doctor or pharmacist** if you are using or have recently used or might use any other medicine.

The following medicines can influence or be influenced by **Metformin**

- **iodinated contrast agents**  
Your doctor will **stop Metformin therapy** before an X-ray examination if these contrast media are used. If he decides your kidney function is normal, you can continue taking **Metformin** 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 **Metformin**. 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 **Metformin** could cause your blood sugar levels to become too low. See under “Take special care with **Metformin**”.

### **METFORMIN 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**

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

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

<b>Sandoz</b>	Business use only	Page 4 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

### Driving and using machines

- When **Metformin** 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 **Metformin**, 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 METFORMIN

#### Metformin 500 mg:

Always take this medicine exactly as your doctor 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.

#### Adults:

- Therecommended starting dose is: 1 **Metformin** tablet 2 to 3 times daily.
- After taking **Metformin** for about 2 weeks your doctor may measure your blood sugar and adjust the dose.
- Maximum dose: 6 **Metformin** tablets\* daily.

#### Children 10 years and over

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

#### Patients 65 years and over

The doctor determines the **Metformin** dose based on your kidney function, as kidney impairment occurrence is high in this group. See also section 2 under “Take special care with **Metformin**”.

#### METFORMIN 850 mg:

Always take **Metformin** exactly as your doctor has told you. You should 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 **Metformin** tablet 2 to 3 times daily
- After taking **Metformin** for about 2 weeks your doctor may measure your blood sugar and adjust the dose.
- Maximum dose: 3000 mg\* metformin hydrochloride daily.

#### Children 10 years and over

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

<b>Sandoz</b>	Business use only	Page 5 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

- Maximum dose: 2000 mg\* metformin hydrochloride daily, divided into 2 or 3 doses.

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

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

See also section 2 under “Take special care with **Metformin**”.

#### **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 **Metformin** than you should**

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

A **Metformin** 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 **Metformin**”. 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 **Metformin****

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 METFORMIN**

Stopping **Metformin** 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 product, ask your doctor or pharmacist.

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

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

**Stop taking Metformin 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

<b>Sandoz</b>	Business use only	Page 6 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

- coma

See chapter 2, under “Take special care with Metformin“.

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 more than 1 in 100 people

- change in taste

**Very rare**, may affect more than 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 **Metformin**
- skin reddening
- itching
- itchy rash
- abnormalities in liver function tests or liver inflammation;  
this may cause:
  - tiredness
  - loss off appetite
  - weight loss
  - yellowing of the skin or whites of the eyes.

Stop taking **Metformin** and tell your doctor straight away if this occurs.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

## 5. How to store METFORMIN

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.

No 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 **METFORMIN** contains

- The **active substance** is metformin hydrochloride.

<b>Sandoz</b>	Business use only	Page 7 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

Each film-coated tablet contains 500 mg / 850 mg metformin hydrochloride equivalent to 390 mg/662.9 mg of metformin base, respectively.

- The other ingredients are:  
Tablet core:  
Povidone K 90, , magnesium stearate.

Film coating:  
hypromellose, macrogol 4000, titanium dioxide

### What **METFORMIN** looks like and contents of the pack NL/H/1170/01-02 + NL/H/1172/01-02/DC

#### **METFORMIN 500 mg**

Round, white, double radius film-coated tablet, embossed "M 500" on one side

**METFORMIN 500 mg** is available in

- HDPE bottles with LDPE caps with 30, 60, 100, 250, 400, 500 film-coated tablets
- PVC aluminium blisters with 28, 30, 50, 56, 60, 84, 90, 100, 120, 180, 250, 270 film-coated tablets.

*Not all pack sizes may be marketed.*

#### **METFORMIN 850 mg**

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

**METFORMIN 850 mg** is available in

- HDPE bottles with LDPE caps with 30, 60, 100, 200, 250, 500 film-coated tablets
- PVC aluminium blisters with 20, 28, 30, 40, 50, 56, 60, 84, 90, 100, 120, 180, 250, 300 film-coated tablets.

### **NL/H/1171/01-02/DC**

#### **METFORMIN 500 mg**

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

**METFORMIN 500 mg** is available in

- HDPE bottles 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.*

#### **METFORMIN 850 mg**

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

**METFORMIN 850 mg** is available in

- HDPE bottles with LDPE caps with polyethylene cap 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 Manufacturer**

**Name: Sandoz GmbH, Kundl**

**Address: Biochemiestrasse 106250.**

**Country: Austria.**

<b>Sandoz</b>	Business use only	Page 8 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

**Manufacturer**

Name: **Lek S.A.**

Company name: **Lek S.A.**

Address: **ul. Podlipie 16, 95-010 Stryków**

Country: **Poland**

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

**NL/H/1172/01-02/DC**

NL: Metformine HCl Sandoz tablet 500 mg

Metformine HCl Sandoz tablet 850 mg

PT: Metformina 1A Pharma

PL: Metformin-1A Pharma

**NL/H/1170/01-02/DC**

BG: Meglucon

BE: Metforsandoz 500 mg filmomhulde tabletten

Metforsandoz 850 mg filmomhulde tabletten

DK: METFORMIN

EE: Glucoral 500mg

Glucoral 850mg

ES: Metformina Sandoz 850 mg comprimidos recubiertos con película EFG

FI: Oramet

FR : METFORMINE SANDOZ 500 MG, COMPRIMÉ PELLICULÉ

METFORMINE SANDOZ 850 MG, COMPRIMÉ PELLICULÉ

IT: METFORMINA SANDOZ GmbH 500 mg compresse rivestite con film

METFORMINA SANDOZ GmbH 850 mg compresse rivestite con film

LV: Glucoral 850 mg apvalkotās tabletes

NL: Metformine HCl Sandoz 500 mg

Metformine HCl Sandoz 850 mg

NO: METFORMIN

PT: Metformina Romac

PL: Etform 500

Etform 850

SE: METFORMIN

SI: Metforminijev klorid Lek 500 mg filmsko obložene tablete

Metforminijev klorid Lek 850 mg filmsko obložene tablete

SK: METFORMIN 500 mg filmom obalené tablety

METFORMIN 850 mg filmom obalené tablety

UK: metformin hydrochloride 500 mg film-coated tablets

metformin hydrochloride 850 mg film-coated tablets

**NL/H/1171/01-02/DC**

IR: 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



<b>Sandoz</b>	Business use only	Page 9 of 9
1.3.1 spc-label-pl - common-pl - 3,247 (NL/H/1171/001/IA/016)		20130722
METFORMIN HYDROCHLORIDE 500 MG; 850 MG FILM-COATED TABLET		721-5715.00 721-5716.00

**This leaflet was last approved in {MM/YYYY}.**

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