

Sandoz	Business use only	Page 1 of 6
1.3.1 spc-label-pl - common-pl - 2,673 (DE/H/1806-1808/001 - harmonized texts (IB/052, IB/053 and II/053/G, II/054/G)		20130708
METFORMIN HYDROCHLORIDE 1 G FILM-COATED TABLET		721-5717.00

Package leaflet: Information for the user

METFORMIN SANDOZ 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 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.

What is in this leaflet

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

1. What Metformin Sandoz is and what it is used for

What Metformin Sandoz is

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

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

What Metformin Sandoz is used for

Metformin 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 Metformin 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 Metformin on its own or together with insulin.

2. What you need to know before you take Metformin Sandoz

Sandoz	Business use only	Page 2 of 6
1.3.1 spc-label-pl - common-pl - 2,673 (DE/H/1806-1808/001 - harmonized texts (IB/052, IB/053 and II/053/G, II/054/G))		20130708
METFORMIN HYDROCHLORIDE 1 G FILM-COATED TABLET		721-5717.00

Do not take Metformin Sandoz

- if you are **allergic** to metformin or any of the other ingredients of this medicine (listed in section 6).
- if you have **kidney or liver problems**.
- if you have **uncontrolled diabetes**, with e.g. severe hyperglycaemia (high blood glucose), nausea, vomiting, dehydration, rapid weight loss 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 unusual fruity odour of the breath.
- 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 **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 you drink a lot of **alcohol**.

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 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 instructions precisely.

Warnings and precautions

Please note the following particular risk of lactic acidosis.

Metformin may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of lactic acidosis is also increased with uncontrolled diabetes, prolonged fasting or alcohol intake. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. **If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking Metformin immediately and contact a doctor or the nearest hospital straight away.**

Metformin on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin 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, visions disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

Other medicines and Metformin

If you need to have an injection of contrast medicines that contain iodine into your bloodstream, for example for examinations such as X-ray or scan, **you must stop taking Metformin for a certain**

Sandoz	Business use only	Page 3 of 6
1.3.1 spc-label-pl - common-pl - 2,673 (DE/H/1806-1808/001 - harmonized texts (IB/052, IB/053 and II/053/G, II/054/G))		20130708
METFORMIN HYDROCHLORIDE 1 G FILM-COATED TABLET		721-5717.00

period of time before and after the examination (see 'Make sure you ask your doctor for advice' above).

Tell your doctor if you take any of the following medicines and Metformin at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of Metformin:

- **diuretics** (used to remove water from the body by making more urine).
- **beta-2 agonists** such as salbutamol or terbutaline (used to treat asthma)
- **corticosteroids** (used to treat a variety of conditions, such as severe inflammation of the skin or in asthma)
- **other medicines used to treat diabetes**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Metformin with alcohol

Do not drink alcohol when you take this medicine. Alcohol may increase the risk of lactic acidosis especially if you have liver problems or if you are undernourished. This also applies to medicines that contain alcohol.

Pregnancy and breast-feeding

During pregnancy, you need insulin to treat your diabetes. Tell your doctor if you are, you think you might be or are planning to become pregnant, so that he or she may change your treatment.

This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

Metformin 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 Metformin 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 heart beat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

3. How to take Metformin

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

Metformin 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.

* Tablets containing 500 mg and 850 mg active substance metformin hydrochloride are also available, for individual dose adjustment.

The recommended dose is:

Children 10 years and over and adolescents usually start with 500 mg or 850 mg Metformin* once a day. The maximum daily dose is 2000 mg taken as 2 or 3 divided doses. Treatment of children between 10 and 12 years of age is only recommended on specific advice from your doctor, as experience in this age group is limited.

Sandoz	Business use only	Page 4 of 6
1.3.1 spc-label-pl - common-pl - 2,673 (DE/H/1806-1808/001 - harmonized texts (IB/052, IB/053 and II/053/G, II/054/G)		20130708
METFORMIN HYDROCHLORIDE 1 G FILM-COATED TABLET		721-5717.00

Adults usually start with 500 mg or 850 mg Metformin* two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses.

If you take insulin too, your doctor will tell you how to start Metformin.

Monitoring

- Your doctor will perform regular blood glucose tests and 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

Take Metformin 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 in the evening (dinner)

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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

If you take more Metformin than you should

If you have taken more Metformin than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. **Contact a doctor or the nearest hospital straight away.**

If you forget to take Metformin Sandoz

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

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. The following side effects may occur:

Very common, 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. It helps if you spread the doses over the day and if you take Metformin with or straight after a meal. **If symptoms continue, stop taking Metformin and talk to your doctor.**

Common, may affect up to 1 in 10 people

- changes in taste.

Sandoz	Business use only	Page 5 of 6
1.3.1 spc-label-pl - common-pl - 2,673 (DE/H/1806-1808/001 - harmonized texts (IB/052, IB/053 and II/053/G, II/054/G)		20130708
METFORMIN HYDROCHLORIDE 1 G FILM-COATED TABLET		721-5717.00

Very rare, 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 vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. **If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking Metformin immediately and contact a doctor or the nearest hospital straight away.**
- 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 and talk to your doctor.
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
- low vitamin B12 levels in the blood.

Children and adolescents

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

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

5. How to store Metformin Sandoz

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.

This medicinal product does not require any special storage conditions.

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

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 Sandoz contains

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

Each film-coated tablet contains 1000 mg metformin hydrochloride equivalent to 780 mg of metformin.

The other ingredients are:

Povidone K 90, magnesium stearate, hypromellose, macrogol 4000, colouring agent titanium dioxide (E171)

What Metformin Sandoz looks like and contents of the pack

Sandoz	Business use only	Page 6 of 6
1.3.1 spc-label-pl - common-pl - 2,673 (DE/H/1806-1808/001 - harmonized texts (IB/052, IB/053 and II/053/G, II/054/G)		20130708
METFORMIN HYDROCHLORIDE 1 G FILM-COATED TABLET		721-5717.00

Metformin are white, oval, biconvex film-coated tablets, scored, embossed "M 1G" on one side . and available in

- PVC aluminium blisters of 20, 30, 60, 90, 120, 180, 200 and 300 tablets
- HDPE bottles with LDPE caps of 100 and 200 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name: Sandoz GmbH, Kundl

Address: Biochemiestrasse 106250.

Country: Austria.

Manufacturer

Name: Lek S.A.

Company name: Lek S.A..

Address: ul. Podlipie 16, 95-010 Stryków

Country: Poland

This leaflet was last revised in {MM/YYYY}.

SEPTEMBER 2013