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.
- 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 any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Metformin is and what it is used for
2. Before you take Metformin
3. How to take Metformin
4. Possible side effects
5. How to store Metformin
6. Further 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. 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.
- 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
- breast-feeding
- 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
- to undergo an X-ray examination with iodinated contrast agents.
See “Using other medicines”.

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.

**Take special care with Metformin**

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
  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.

**Using other medicines**

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

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**

Reduction in 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”.

**Taking Metformin with food and drink**

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 if you are breast-feeding.

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

**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.

**Important information about some of the ingredients of Metformin**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. **HOW TO TAKE METFORMIN**

Metformin 500 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 850 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: 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.
- 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.

An Metformin overdose of 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 occuring 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, Metformin can cause side effects, although not everybody gets them.

Side effects can occur with the following frequencies:

Very common, occurs in more than 1 per 10 users.
- 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, occurs in 1 to 10 per 100 users
- change in taste

Very rare, occurs in fewer than 1 per 10,000 users
- reduction in the vitamin B₁₂ uptake in the intestine when treated for a long-term period with Metformin
- lactic acidosis, a severe disorder of blood over-acidification
  See end of subsection “Do not take Metformin”.
  If this happens, stop taking Metformin immediately and inform your doctor straight away.
- skin reddening
• itching
• itchy rash

Frequency not known
• 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 Metformin and tell your doctor straight away if this occurs.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE METFORMIN
Keep out of the reach and sight of children.

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

Store in the original pack in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What Metformin contains
- The active substance is metformin hydrochloride.
  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:
  microcrystalline cellulose, sodium starch glycollate (type A), copovidone, colloidal anhydrous silica, magnesium stearate.

  Film coating:
  lactose monohydrate, 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
White, oblong film-coated tablets with a scoreline on both sides and “M 500” on one side. The tablets can be divided into equal halves

Metformin 850 mg
White, oblong film-coated tablet with a scoreline on both sides and “M 850” on one side. The film-coated tablet can be divided into equal halves.
Polyethylene bottles with polyethylene caps with 30, 60, 100, 250, 400, 500 film-coated tablets.
PVC/PVDC/aluminium or PP/aluminium blister with 28, 30, 56, 60, 84, 90, 100, 120, 180, 250, 270 film-coated tablets.

Metformin 850 mg:
Polyethylene bottles with polyethylene caps with 30, 60, 100, 200, 250, 500 film-coated tablets.
PVC/PVDC/aluminium or PP/aluminium blister with 20, 28, 30, 40, 50, 56, 60, 84, 90, 100, 120, 180, 250, 300 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

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
PL: Metformin-1A Pharma

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

NL/H/1170/01-02/DC
BG: Metformin Sandoz
BE: Metformine Sandoz 500 mg filmomhulde tabletten
     Metformine Sandoz 850 mg filmomhulde tabletten
DK: Metformin Sandoz
ES: Metformina Salutas 850 mg comprimidos recubiertos con película EFG
FI: Metformin Sandoz
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
NL: Metformine HCl Sandoz 500 mg
     Metformine HCl Sandoz 850 mg
NO: Metformin Sandoz
PT: Metformina Romac
PL: Etform 500
This leaflet was last approved in {MM/YYYY}. 