Package leaflet: Information for the user

Metformine HCl CF 1000 mg, filmomhulde tabletten

metforminehydrochloride

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 <Product name> is and what it is used for

<Product name> tablets contain the active ingredient metformin, a medicine to treat diabetes. It belongs to a group of medicines called biguanides.

Insulin is a hormone produced by the pancreas that enables your body to 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. <Product name> helps to lower your blood glucose to as normal a level as possible.

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

<Product name> 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 <Product name> 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 <Product name> on its own or together with insulin.

2. What you need to know before you take <Product name>

DO NOT take <Product name>
- if you are allergic to metformin or any of the other ingredients of this medicine (listed in section 6)
- if you have liver problems
- if you have severely reduced kidney function

- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood sugar), 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 lost too much water from your body (dehydration), e.g. from 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')
- if you have a severe infection, such as an infection affecting your lung or bronchial system or your kidneys. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions')
- if you are treated for acute heart failure or have recently had a heart attack or 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')
- 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
- major surgery

You must stop taking <Product name> 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

<Product name> 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 <Product name> 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 breathing
- reduced body temperature and slower heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Stop taking <Product name> 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.

Please note the following
- If you need to have major surgery, you must stop taking <Product name> during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with <Product name>.

- <Product name> on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take <Product name> 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 heartbeat, vision disorders or difficulty concentrating, it usually helps to eat or drink something containing sugar.

- During treatment with <Product name>, 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 <Product name>

If you need to have an injection of **a contrast medium** that contains iodine into your bloodstream, e.g. for an X-ray or scan, you must stop taking <Product name> before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with <Product name>.

Tell your doctor 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 dosage of <Product name>. It is especially important to mention the following:
- 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**)
- **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)
- medicines that may change the amount of <Product name> in your blood, especially if you have reduced kidney function (such as **verapamil**, **rifampicin**, **cimetidine**, **dolutegravir**, **ranolazine**, **trimethoprim**, **vandetanib**, **isavuconazole**, **crizotinib**, **olaparib**)
- other medicines used to treat diabetes

<Product name> with alcohol
Avoid excessive alcohol intake while taking <Product name> since this may increase the risk of lactic acidosis (see section ‘Warnings and precautions’).

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, speak to your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels.
This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines
<Product name> taken 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 <Product name> 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 concentrating. Do not drive or use machines if you start to feel these symptoms.

3. How to take <Product name>

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

Recommended dose

Children 10 years and over and adolescents
Usually start with 500 mg or 850 mg <Product name> once a day. The maximum daily dose is 2 000 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.

Adults
Usually start with 500 mg or 850 mg <Product name> two or three times a day. The maximum daily dose is 3 000 mg taken as 3 divided doses. If you have reduced kidney function, your doctor may prescribe a lower dose.

If you take insulin too, your doctor will tell you how to start <Product name>.

<Product name> 1 000 mg film-coated tablets:
The tablets can be divided into equal doses.

Monitoring
- Your doctor will perform regular blood glucose tests and will adapt your dose of <Product name> 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.

Method of administration
The tablets are for oral use.
Take <Product name> 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).

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

If you take more <Product name> than you should
If you have taken more <Product name> than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific such as vomiting, abdominal pain with

muscle cramps, a general feeling of not being well with severe tiredness, and difficulty breathing. Further symptoms are reduced body temperature and heartbeat. **If you experience some of these symptoms, you should seek immediately medical attention, as lactic acidosis may lead to coma. Stop taking <Product name> immediately and contact a doctor or the nearest hospital straight away.**

If you forget to take <Product name>
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 medicine, 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:

<Product name> 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 <Product name> and contact a doctor or the nearest hospital immediately**, as lactic acidosis 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 breathing
- reduced body temperature and slower heartbeat

Other possible side effects are listed by frequency as follows:

Very common (may affect more than 1 in 10 people)
- digestive problems, such as feeling sick (nausea), being sick (vomiting), diarrhoea, stomach ache (abdominal pain) and loss of appetite
  These side effects most often happen at the beginning of treatment with metformin. It helps if you spread the doses over the day and if you take <Product name> with or straight after a meal. **If symptoms continue, stop taking <Product name> and talk to your doctor**.

Common (may affect up to 1 in 10 people)
- changes in taste
- decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems

Very rare (may affect up to 1 in 10,000 people)
- 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 <Product name> and talk to your doctor**
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives)

Children and adolescents

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

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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 pack after EXP. The expiry date refers to the last day of that month.
[HDPE bottles only]: After the first opening, the bottle may be used for up to 90 days.

This medicinal product does not require any special storage condition.
Do not throw away any 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 <Product name> contains

<Product name> 1 000 mg film-coated tablets
The active substance is metformin hydrochloride. One film-coated tablet contains 1 000 mg metformin hydrochloride corresponding to 780 mg metformin base. The other ingredients are Magnesium Stearate, Povidone (E1201), Hypromellose 2910 (E464), Titanium dioxide (E171) and Macrogol 3350.

What <Product name> looks like and contents of the pack

Description

<Product name> 1 000 mg film-coated tablets: White to off white, oval, biconvex, film-coated tablets debossed with “003” on one side and “1000” on the other side and with a bisect line on both sides The tablet can be divided into equal doses. Approximate dimension of the tablets are 19 mm length and 10 mm width.

Contents of the pack
[DE/H/7128/001-003/DC]
<Product name> 1000 mg film-coated tablets
Blister (PVC/AL) of 18, 30, 50, 60, 90, 120, 180 and 1500 film-coated tablets
HDPE Bottles with polypropylene child-resistant closure, white opaque cap, translucent inner cap and liner containing 100 film-coated tablets
HDPE Bottles with polypropylene screw closure, white opaque cap, translucent inner cap and liner containing 500 film-coated tablets

Pack sizes 500 tablets (in HDPE Bottles) and 1500 tablets (in Blister) are intended for hospital and dose dispensing/medicinal rolls only.

Not all the pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Centrafarm B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

Fabrikant:
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

Centrafarm Services B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

In het register ingeschreven onder
Metformine HCl CF 1000 mg, filmomhulde tabletten RVG 128396

Dit medicijn is geregistreerd in lidstaten van de EEA onder de volgende namen:

België	Metformin EG 1000 mg filmomhulde tabletten
Denemarken	Forminet
Duitsland	Metformin AL 1000 mg Filmtabletten
Finland	Forminet 1000 mg tabletti, kalvopäällysteinen
Frankrijk	METFORMINE EG LABO 1000 mg, comprimé
Hongarije	Metformin Stada 1000 mg filmtabletta
IJsland	Forminet 1000 mg filmuhúðaðar töflur
Luxemburg	Metformin EG 1000 mg comprimés pelliculés
Nederland	Metformine HCl CF 1000 mg, filmomhulde tabletten
Noorwegen	Forminet
Polen	Metformin hydrochloride STADA
Portugal	Metformina Ciclum Farma
Slowakije	Metformin STADA 1000 mg filmom obalené tablety
Tsjechië	STADAMET NEO
Spanje	Metformina STADAFARMA 1000 mg comprimidos
Zweden	Forminet 1000 mg filmdragerade tabletter

Deze bijsluiter is voor het laatst goedgekeurd in april 2023.