

PACKAGE LEAFLET: INFORMATION FOR THE USER

SIOFOR 1000

1000mg film-coated tablets

For use in children from 10 years and adults

METFORMIN HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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?

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1. WHAT SIOFOR 850 IS AND WHAT IS IT USED FOR

What SIOFOR 1000 is

SIOFOR 1000 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. SIOFOR 1000 helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking SIOFOR 1000 over a long period of time also helps to lower the risk of complications associated with diabetes. SIOFOR 1000 is associated with either a stable body weight or modest weight loss.

What SIOFOR 1000 is used for

SIOFOR 1000 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 SIOFOR 1000 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 SIOFOR 1000 on its own or together with insulin.

2. BEFORE YOU TAKE SIOFOR 850

Do not take SIOFOR 1000:

if you are allergic to metformin hydrochloride 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.

Warnings and precautions

Talk to your doctor before taking SIOFOR 1000.

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 SIOFOR 1000 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.

Please note the following particular risk of lactic acidosis.

SIOFOR 1000 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 SIOFOR 1000 immediately and contact a doctor or the nearest hospital straight away.**

SIOFOR 1000 on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take SIOFOR 1000 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, vision disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

Other medicines and SIOFOR 1000

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 SIOFOR 1000 for a certain 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 SIOFOR 1000 at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of SIOFOR 1000:

- 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
- ranolazine (used to treat angina pectoris) or cimetidine (used to treat stomach problems)

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

SIOFOR 1000 and 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.

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, so that he or she may change your treatment.

This medicine is not recommended if you are breast-feeding.

Driving and using machines

SIOFOR 1000 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 SIOFOR 1000 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 SIOFOR 850

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

SIOFOR 1000 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

Adults usually start with ½ a Siofor film-coated tablet (equivalent to 500 mg metformin hydrochloride) 2 to 3 times daily or 850 mg metformin hydrochloride 2 to 3 times daily (this dosage is not possible with SIOFOR 1000).

The maximum daily dose is 1 SIOFOR 1000 film-coated tablet 3 times per day.

Use in children and adolescents

Children 10 years and over and adolescents usually start with ½ a SIOFOR 1000 film-coated tablet (equivalent to 500 mg metformin hydrochloride) once daily or 850 mg metformin hydrochloride once daily (this dosage is not possible with SIOFOR 1000).

The maximum daily dose is 1 SIOFOR 1000 film-coated tablet twice per day. 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.

If you take insulin too, your doctor will tell you how to start SIOFOR 1000.

Monitoring

Your doctor will perform regular blood glucose tests and will adapt your dose of SIOFOR 1000 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 divide your SIOFOR 1000 film-coated tablet

The tablet can be divided into equal doses.

Due to its tablet form, SIOFOR 1000 enables easy and accurate dividing of the film-coated tablet. The film-coated tablets can optionally be divided with two hands, or by placing them with the larger break-mark facing downwards on a hard, flat surface and applying thumb pressure (see figure).



How to take SIOFOR 1000 film-coated tablets

Take the tablets 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 SIOFOR 1000 is too strong or too weak, talk to your doctor or pharmacist.

If you take more SIOFOR 1000 than you should

If you have taken more SIOFOR 1000 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 SIOFOR 1000

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:

Very common side effects (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 SIOFOR 1000. It helps if you spread the doses over the day and if you take the tablets with or straight after a meal. **If symptoms continue, stop taking SIOFOR 1000 and talk to your doctor.**

Common side effects (may affect up to 1 in 10 people)

changes in taste.

Very rare side effects (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 SIOFOR 1000 immediately and contact a doctor or the nearest hospital straight away.**

skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

low vitamin B12 levels in the blood.

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 this medicine and talk to your doctor.**

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 or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SIOFOR 850

Keep this medicine out of the sight and reach of children. If a child is treated with SIOFOR 1000, parents and caregivers are advised to oversee how this medicine is used.

Do not use this medicine after the expiry date which is stated on the blister and folding box after EXP. 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 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. FURTHER INFORMATION

What SIOFOR 1000 contains

The active substance is metformin hydrochloride.

Each film-coated tablet contains 1,000 mg metformin hydrochloride (equivalent to 780 mg metformin).

The other ingredients are hypromellose, povidone K 25, magnesium stearate (Ph. Eur.) [vegetable], macrogol 6000, titanium dioxide (E 171).

What SIOFOR 1000 looks like and contents of the pack

White, oblong tablets domed on both sides with snap-tab break-mark on one side and breaking notch on the other.

The tablet can be divided into equal doses (see Section 3 for instructions on dividing).

SIOFOR 1000 is available in packages with 10, 30, 60, 90 and 120 film-coated tablets. Not all pack sizes may be marketed.