

PACKAGE LEAFLET: INFORMATION FOR THE USER

SIOFOR 500

500mg film-coated tablets

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?

1. What SIOFOR 500 is and what it is used for
2. Before you take SIOFOR 500
3. How to take SIOFOR 500
4. Possible side effects
5. How to store SIOFOR 500

1. WHAT SIOFOR 500 IS AND WHAT IS IT USED FOR

SIOFOR 500 contains the active substance metformin. It belongs to a group of medicines called biguanides for treating type 2 diabetes mellitus (non-insulin-dependent diabetes) in adults and in children of 10 years of age or in children and adolescents above 10 years.

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

If you are overweight, taking SIOFOR 500 also helps to lower the risk of complications associated with diabetes. SIOFOR 500 is associated with a consistent and substantial reduction in body weight.

What SIOFOR 500 is used for?

SIOFOR 500 is a medicine for

- the treatment of prediabetes in adults who are at high-risk to develop overt type 2 diabetes mellitus i.e., subjects with impaired glucose tolerance (IGT) and impaired fasting plasma glucose (IFG) and any of the following: <60 years of age, BMI \geq 30 kg/m², family history of diabetes in first degree relatives, elevated triglycerides, reduced HDL cholesterol, hypertension, HbA_{1c} \geq 6.0%, history of gestational diabetes.
- the treatment of type 2 diabetes mellitus, particularly in overweight patients, to adequately control blood glucose.
- Adults with type 2 diabetes mellitus can take SIOFOR 500 on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).
- Children 10 years and over and adolescents with type 2 diabetes mellitus can take SIOFOR 500 on its own or together with insulin.

The treatment with Siofor should be supported by dietary management and exercise.

2. BEFORE YOU TAKE SIOFOR 500

Do not take SIOFOR 500:

- if you are allergic to metformin or any of the other ingredients of this medicine
- 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. 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 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 500.

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 500 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 500 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 500 immediately and contact a doctor or the nearest hospital straight away.**

SIOFOR 500 on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take SIOFOR 500 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.

Monitoring

- Your doctor will perform regular blood glucose tests and will adapt your dose of SIOFOR 500 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.

Other medicines and SIOFOR 500

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

Other medicines and SIOFOR 500

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

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 500 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 500 at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of SIOFOR 500:

- water pills (so called 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 to treat diabetes
- ranolazine (used to treat angina pectoris) or cimetidine (used to treat stomach problems)
- medicines containing alcohol

SIOFOR 500 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, breast-feeding and fertility

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.

Pregnancy

During pregnancy, you need insulin to treat your diabetes.

Breast-feeding

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

Driving and using machines

SIOFOR 500 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 500 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 in concentration. Do not drive or use machines if you start to feel these symptoms.

3. HOW TO TAKE SIOFOR 500

Adults usually start with 1 SIOFOR 500 film-coated tablet 2 to 3 times a day (equivalent to 1,000 or 1,500 mg metformin hydrochloride a day) or 850 mg metformin hydrochloride 2 to 3 times a day (this dosage is not possible with SIOFOR 500).

The maximum daily dose is 2 SIOFOR 500 film-coated tablets 3 times a day (equivalent to 3,000 mg metformin hydrochloride a day). **Use in children and adolescents**

Children 10 years and over and adolescents usually start with 1 SIOFOR 500 film-coated tablet once a day (equivalent to 500 mg metformin hydrochloride a day) or 850 mg metformin hydrochloride once a day (this dosage is not possible with SIOFOR 500).

The maximum daily dose is 2 SIOFOR 500 film-coated tablets twice per day (equivalent to 2,000 mg metformin hydrochloride a 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 500.

Monotherapy (prediabetes)

The recommended starting dose in prediabetes is one film-coated tablet (500 mg) what can be increased for twice daily if necessary (twice daily 500 mg).

The film-coated tablets should be taken during or after meals.

A slow increase of dose may improve gastro-intestinal tolerability.

Doctor evaluate, if treatment should be continued, based on to regular glycemic control and risk factors.

How to take SIOFOR 500 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 500 is too strong or too weak, talk to your doctor or pharmacist.

If you take more SIOFOR 500 than you should

If you have taken more SIOFOR 500 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 500

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:

Important undesirable effects or symptoms which you should be aware of and precautions in case they occur:

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 SIOFOR 500 immediately and contact a doctor or the nearest hospital straight away.

Other possible side effects:

Very common (may affect more than 1 in 10 people)

- digestive problems, such as nausea, vomiting, diarrhoea, bellyache (abdominal pain) and loss of appetite. These side effects most often happen at the beginning of the treatment with SIOFOR 500. 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 500 and talk to your doctor.

Common (may affect up to 1 in 10 people)

- changes in taste

Very rare (may affect up to 1 in 10,000 people)

- skin reactions such as redness of the skin (erythema), itching or an itchy rash (urticaria)
- 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 SIOFOR 500 and talk to your doctor.**

Additional side effects in 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 500

Keep this medicine out of the sight and reach of children.

If a child is treated with SIOFOR 500, 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 on the label and carton after (Expiration, Exp.:). The expiry date refers to the last day of that month.

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.