

SIOFOR® 1000 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Siofor® 1000 is and what it is used for
2. Before you take Siofor® 1000
3. How to take Siofor® 1000
4. Possible side effects
5. How to store Siofor® 1000
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1. WHAT SIOFOR® 1000 IS AND WHAT IT IS 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.

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® 1000

Do not take Siofor® 1000

- if you are allergic (hypersensitive) to metformin or any of the other ingredients of this medicine (see 'What Siofor® 1000 contains' in section 6)
- if you have kidney or liver problems
- if you have uncontrolled diabetes, such as severe hyperglycaemia 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 have 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 'Take special care with Siofor® 1000' 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 'Take special care with Siofor® 1000' 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 'Take special care with Siofor® 1000' 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 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.

Take special care with Siofor® 1000

Siofor® 1000 may cause a very rare, but serious complication called lactic acidosis, 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 treatment. Stop taking Siofor® 1000 immediately and tell your doctor 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, glinides), 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.

Taking 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® 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)

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

Taking Siofor® 1000 with food and drink

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.

It is not recommended to take Siofor® 1000 during breast-feeding. Your doctor will decide whether you should stop breast-feeding while you are treated with Siofor® 1000.

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, glinides). Symptoms of hypoglycaemia include weakness, dizziness,

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3. HOW TO TAKE SIOFOR[®] 1000

Always take Siofor[®] 1000 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.

Usual dose

Children 10 years and over and adolescents usually start with ½ a Siofor[®] 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.

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.

If you take insulin too, your doctor will tell you how to start Siofor[®] 1000.

Monitoring

- Your doctor 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

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. Talk to your doctor or pharmacist 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Siofor[®] 1000 can cause side effects, although not everybody gets them. The following side effects may occur:

Very common side effects (in 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 (in less than 1 in 10 people)

- changes in taste

Very rare side effects (in less than 1 in 10,000 people)

- lactic acidosis. This is a very rare but serious complication particularly if your kidneys are not working properly. If you get this complication, you will need immediate treatment.

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, stop taking Siofor[®] 1000 immediately and tell your doctor straight away.**

- 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 this medicine.**

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 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 SIOFOR® 1000

Keep out of the reach and sight of children. If a child is treated with Siofor® 1000, 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 Siofor® 1000 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.

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 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 halves (see Section 3 for instructions on dividing).

Siofor® 1000 is available in packages with 30, 60, and 120 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Laboratori Guidotti S.p.A. – Pise, Italy

Manufacturer Berlin-Chemie AG – Berlin, Germany

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