

DIABIPHAGE® 850 MG/ film-coated tablets
DIABIPHAGE® 1000 MG/ film-coated scored
Metformin hydrochloride

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 your 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 DIABIPHAGE® is and what it is used for.
2. What you need to know before you take DIABIPHAGE®.
3. How to take DIABIPHAGE®.
4. Possible side effects.
5. How to store DIABIPHAGE®.
6. Contents of the pack and other information.

1. What DIABIPHAGE® is and what it is used for

DIABIPHAGE® contains the active substance metformin hydrochloride, 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. DIABIPHAGE® helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking DIABIPHAGE® over a long period of time also helps to lower the risk of complications associated with diabetes.

DIABIPHAGE® is associated with either a stable body weight or modest weight loss.

What DIABIPHAGE® is used for

DIABIPHAGE® 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 DIABIPHAGE® 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 DIABIPHAGE® on its own or together with insulin.

2. What you need to know before you take DIABIPHAGE®

- Do not take DIABIPHAGE®**
- if you are allergic to metformin 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 can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or unusual fruity odour of the breath
 - if you lose 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 or pharmacist before taking DIABIPHAGE®.

Please note the following particular risk of lactic acidosis:

DIABIPHAGE® 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 hospital treatment, as lactic acidosis may lead to coma. Stop taking DIABIPHAGE® immediately and contact a doctor or the nearest hospital straight away.

The risk of lactic acidosis is increased if you:

- have poorly controlled diabetes
- have metabolic ketone bodies (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue, feeling sick (nausea), frequent urination and muscular stiffness)
- undergo a prolonged period of fasting
- drink a lot of alcohol
- have liver problems
- have low levels of oxygen in the blood.

You need to eat carbohydrates regularly throughout the day. If your doctor has given you advice on your diet, you need to continue to follow this.

DIABIPHAGE® on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take DIABIPHAGE® together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulfonylureas, insulin, meglitinides), 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.

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 DIABIPHAGE® 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.

Children and adolescents

DIABIPHAGE® is not recommended for use in children under 10 years of age.

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.

Other medicines and Metformin hydrochloride

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 Metformin hydrochloride 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 Metformin hydrochloride at the same time. You may need more frequent blood glucose tests or your doctor may adjust the dosage of Metformin hydrochloride:
- diuretics (used to remove water from the body by making more urine)
 - beta2-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
- Metformin hydrochloride with drink 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. Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby, so that he or she may change your treatment. This

medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Metformin hydrochloride 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 Metformin hydrochloride together with other medicines to treat diabetes that can cause hypoglycaemia (such as sulfonylureas, 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 Metformin hydrochloride

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

Metformin hydrochloride 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.

The recommended dose in adults is 500 mg or 850 mg Metformin hydrochloride two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses.

If you take insulin too, your doctor will tell you how to start Metformin hydrochloride.

Use in children 10 years of age and over and adolescents

Children 10 years and over and adolescents usually start with 500 mg or 850 mg Metformin hydrochloride once a day. The maximum daily dose is 2000 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.

Monitoring

- Your doctor will perform regular blood glucose tests and will adapt your dose of Metformin hydrochloride 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

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).

The 1000 mg tablet can be divided into equal doses.

If, after some time, you think that the effect of Metformin hydrochloride is too strong or too weak, talk to your doctor or pharmacist.

If you take more Metformin hydrochloride than you should

Do not crush or chew the tablets. Swallow each tablet with a glass of water.

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 Metformin hydrochloride

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop taking Metformin hydrochloride

If you suddenly stop taking Metformin hydrochloride your blood glucose level may rise. Speak to your doctor before stopping this medicine.

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.

If you think you may have any of the following side effects, stop taking this medicine immediately and go to your nearest hospital emergency room straight away. These side effects are very rare (may affect up to 1 in 10,000 people) but you may need immediate medical attention:

- 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. Lactic acidosis can lead to coma
- 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).

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 Metformin hydrochloride. 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 Metformin hydrochloride and talk to your doctor.
- changes in taste.

Very rare side effects (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.

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. You can also report side effects directly via the national reporting system listed in Appendix V (To be completed nationally). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metformin hydrochloride

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 carton, blister and bottle 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 any medicines you no longer use. These measures will help to protect the environment.

Shelf life: 36 months.

6. Contents of the pack and other information

DIABIPHAGE® 850 mg		DIABIPHAGE® 1000 mg
Active substance :		
Metformine hydrochloride	850 mg	1000 mg
Excipients :		
Povidone K30, Povidone K90, pregelatinized starch, magnesium stearate, Crospovidone, white Opadry II.	polyvinylpyrrolidone, microcrystalline cellulose, maize starch, magnesium stearate, colloidal silica anhydrous, white Opadry II.	

What DIABIPHAGE® looks like and contents of the pack

DIABIPHAGE® 850 MG, white film-coated tablets. They are supplied in pack size of 60 per pack.

DIABIPHAGE® 1000 MG, white film-coated scored tablets. They are supplied in pack size of 60 per pack.

MARKETING AUTHORISATION NUMBER(S):
DIABIPHAGE® 850 MG: 923 387 1
DIABIPHAGE® 1000 MG: 923 387 2

Delivery conditions : List 1.

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This is a Medication

Medication is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medications out of reach of children

