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Package leaflet: Information for the user

Metformin Hydrochloride Somex Pharma 500 mg Prolonged-release tablets

Metformin hydrochloride

This medicine is intended for **adult** patients only.

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 or nurse.
- This medicine has been prescribed for you only. Do not pass it onto 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What Metformin Hydrochloride Somex Pharma tablet is and what it is used for
2. What you need to know before you take Metformin Hydrochloride Somex Pharma tablet
3. How to take Metformin Hydrochloride Somex Pharma tablet
4. Possible side effects
5. How to store Metformin Hydrochloride Somex Pharma tablet
6. Contents of the pack and other information

1. What Metformin Hydrochloride Somex Pharma tablet is and what it is used for

Metformin Hydrochloride Somex Pharma prolonged-release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of diabetes. Metformin Hydrochloride Somex Pharma tablet is used for the treatment of Type 2 (non-insulin dependent) diabetes mellitus when diet and exercise changes alone have not been enough to control blood glucose (sugar). Insulin is a hormone that enables body tissues to take glucose from the blood and to use it for energy or for storage for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long-term problems so it is important that you continue to take your medicine, even though you may not have any obvious symptoms. Metformin Hydrochloride Somex Pharma tablet makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Metformin Hydrochloride Somex Pharma tablet is associated with either a stable body weight or modest weight loss. Metformin Hydrochloride Somex Pharma Prolonged-release Tablets are specially made to release the drug slowly in your body and therefore are different to many other types of tablets containing metformin.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Metformin Hydrochloride Somex Pharma Tablet

Do not take Metformin Hydrochloride Somex Pharma tablet:

- if you are allergic to metformin or to any of the other ingredients of this medicine (listed in section 6). An allergic reaction may cause a rash, itching or shortness of breath.
- if you have ketosis (this is a symptom of uncontrolled diabetes in which substances called 'ketone bodies' accumulate in the blood—you may notice that your breath has an unusual, fruity odour).
- if you have kidney or liver problems (glomerular filtration rate (GFR) below 45 ml/min).
- if you have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration. 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 kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').

- if you have been treated for acute heart problems or have recently had a heart attack or have severe circulatory problems or 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 are a heavy drinker of alcohol.
- if you are under 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Metformin Hydrochloride Somex Pharma tablet

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. (See below under other medicines and Metformin Hydrochloride Somex Pharma tablet).
- you need to have major surgery.

You must stop taking Metformin Hydrochloride Somex Pharma tablet 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.

After you have started taking your medicine:

If you have diabetes you should have your blood or urine tested for sugar regularly. You should return to your doctor at least once a year to check the function of your kidneys (more often if you are elderly or if you have kidney problems).

Please note the following particular risk of lactic acidosis.

Metformin Hydrochloride Somex Pharma tablet may cause a very rare, but very serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, prolonged fasting or alcohol intake, body fluid deficit (dehydration) due to severe diarrhoea or vomiting, liver problems and any medical conditions in which a region of the body is deprived with a lack of oxygen supply (such as acute severe heart diseases).

It is important to you to comply with your medication intake, dietary instructions and regular exercise program because this can reduce the risk of lactic acidosis.

The onset of lactic acidosis can be subtle and the symptoms can be non-specific such as vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness and difficulty in breathing. Further symptoms are reduced body temperature and heart beat.

If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma. Stop taking Metformin Hydrochloride Somex Pharma tablet immediately and contact a doctor or the nearest hospital straight away.

You may see some remains of the tablets in your stools. Do not worry—this is normal for this type of tablet.

You should continue to follow any dietary advice that your doctor has given you and you should make sure that you eat carbohydrates regularly throughout the day.

Do not stop taking this medicine without speaking to your doctor.

Children and adolescents

This medicine is intended for adult patients only.

Other medicines and Metformin Hydrochloride Somex Pharma tablet:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without prescription.

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 Somex Pharma tablet for a certain period of time before and after (at least 48 hours) the examination (see 'Make sure you ask your doctor for advice' above).

If you are taking any of the following medicines, your blood sugar levels may need to be checked more often and your dose adjusted:

- Steroids such as prednisolone, mometasone, beclometasone.
- Diuretics (water tablets) such as furosemide.
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure.

Epinephrine is also included in some dental anaesthetics.

You should avoid drinking alcohol and using alcohol-containing medicines as this will increase the risk of lactic acidosis (see section 4 possible side effects).

Metformin Hydrochloride Somex Pharma tablet with food, drink:

You should take Metformin Hydrochloride Somex Pharma tablet with or immediately after food.

Pregnancy and breast-feeding and fertility

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

Metformin Hydrochloride Somex Pharma tablet taken on its own does not cause 'hypos' (symptoms of low blood sugar or hypoglycaemia, such as faintness, confusion and increased sweating) and therefore should not affect your ability to drive or use machinery.

You should be aware, however, that Metformin Hydrochloride Somex Pharma tablet taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

3. How to take Metformin Hydrochloride Somex Pharma tablet

Your doctor may prescribe Metformin Hydrochloride Somex Pharma tablet for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

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

Swallow the tablets whole with a glass of water, do not chew.

The Recommended dose is

Usually you will start treatment with 500mg Metformin Hydrochloride Somex Pharma tablet daily. After you have been taking Metformin Hydrochloride Somex Pharma tablet for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 mg of Metformin Hydrochloride Somex Pharma tablet.

In renal impaired patients with a GFR between 45 and 60 ml/min, the starting dose is 500 mg or 750 mg Metformin Hydrochloride Somex Pharma tablet once daily. The maximum dose is 1000 mg daily. The renal function should be closely monitored (every 3 – 6 months).

Normally, you should take the tablets once a day, with your evening meal. In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

Use in children and adolescents

This medicine is intended for adult patients only.

If you take more Metformin Hydrochloride Somex Pharma tablet than you should

If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis is more likely. Symptoms of lactic acidosis are non-specific, such as vomiting, bellyache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heart beat. If you experience some of these symptoms, you should immediately seek medical

attention, as lactic acidosis may lead to coma. Stop taking Metformin Hydrochloride Somex Pharma tablet immediately and contact a doctor or the nearest hospital straightaway.

If you forget to take Metformin Hydrochloride Somex Pharma tablet

Take it as soon as you remember with some food. Do not take a double dose to make up for a forgotten dose.

If you stop taking Metformin Hydrochloride Somex Pharma tablet

Do not stop taking this medicine without speaking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following, stop taking Metformin Hydrochloride Somex Pharma tablet and see your doctor immediately:

- unexpected weight loss
- very severe nausea or vomiting
- a general feeling of not being well with severe tiredness
- reduced heart beat
- very fast breathing which you cannot stop
- stomach pains with muscle cramps or feeling cold

These can be signs of serious problems with your diabetes and may mean you have a very rare side effect called "lactic acidosis" (too much acid in the blood). If this happens see a doctor as you will need treatment straight away.

- abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice. If you develop yellowing of the eyes and/or skin contact your doctor immediately.

Other possible side effects are listed by frequency as follows:

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

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. If you get these, do not stop taking the tablets as these symptoms will normally go away in about 2 weeks. It helps if you take the tablets with or immediately after a meal.

Common (may affect up to 1 in 10 people):

- Taste disturbance
- 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):

- Skin rashes including redness, itching and hives.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metformin Hydrochloride Somex Pharma tablet

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.

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. Contents of the pack and other information

What Metformin Hydrochloride Somex Pharma tablet contains

The active substance is metformin hydrochloride. Each prolonged release tablet contains 500mg of metformin hydrochloride.

The other ingredients are magnesium stearate, carmellose sodium and hypromellose and microcrystalline cellulose.

What Metformin Hydrochloride Somex Pharma tablet looks like and contents of the pack

The tablets are white to off-white and capsule-shaped with '500' engraved on one side and SP on the other side.

Metformin Hydrochloride Somex Pharma tablet is supplied in packs of 28 and 56 prolonged-release tablets.

Marketing Authorisation Holder

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Manufacturer

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