

PACKAGE LEAFLET: INFORMATION FOR THE USER

METSAFE ER (METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS USP)

This medicine is intended for adult patients only.
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.

In this leaflet:

1. What METSAFE ER is and what it is used for
2. Before you take METSAFE ER
3. How to take METSAFE ER
4. Possible side effects
5. How to store METSAFE ER
6. Further information

1. WHAT METSAFE ER IS AND WHAT IT IS USED FOR:

METSAFE ER prolonged release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of diabetes. METSAFE ER 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. METSAFE ER makes the body more sensitive to insulin and helps return to normal the way your body uses glucose. METSAFE ER is associated with either a stable body weight or modest weight loss. METSAFE ER Prolonged Release Tablets are specially made to release the drug slowly in your body and therefore are different to many other types of tablet containing metformin.

2. BEFORE YOU TAKE METSAFE ER:

Do not take METSAFE ER if:

- you are allergic to metformin or to any of the other ingredients which are listed later on in the leaflet (see under '6. Further information').
- 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).
- you have long-term kidney or liver problems.
- you have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration.
- you have a severe infection or have recently suffered a severe injury.
- you have been treated for heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties.
- you are a heavy drinker of alcohol.
- you are under 18 years of age.

Take special care with METSAFE ER .

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).

If you start to lose weight unexpectedly or suffer severe nausea or vomiting, uncontrolled rapid breathing or abdominal pains, stop taking the medicine and tell your doctor straight away. This can be a sign of a rare, but serious, complication with your diabetes called 'lactic acidosis' which means there is too much acid in the blood (see also under '4. Possible side effects').

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

If you need to have an X-ray examination involving the injection of a dye, tell the doctor that you take METSAFE ER as you may need to stop taking it for a few days afterwards.

Tell your doctor if you are going to have an operation under general anaesthetic, as you may need to stop taking METSAFE ER for a couple of days before and after the procedure.

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.

Taking METSAFE ER with other medicines:

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

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 under '4. Possible side effects').

Taking METSAFE ER with food and drink:

You should take METSAFE ER with or immediately after food.

Pregnancy and breast-feeding:

Do not take METSAFE ER if you are pregnant or breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

METSAFE ER 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 METSAFE ER 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 METSAFE ER

Your doctor may prescribe METSAFE ER for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

Always take METSAFE ER exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water, do not chew. Usually you will start treatment with 500 milligrams METSAFE ER daily. After you have been taking METSAFE ER for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 mg of METSAFE ER. 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.

If you take more METSAFE ER 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 and this is a medical emergency requiring treatment in hospital (see also under '4. Possible side effects').

If you forget to take METSAFE ER

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, METSAFE ER can cause side effects, although not everybody gets them. If you notice any of the following, stop taking METSAFE ER and see your doctor immediately:

- unexpected weight loss
- very severe nausea or vomiting
- very fast breathing which you cannot stop
- stomach pains 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 (affects more than 1 person in 10):

- 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 (affects less than 1 person in 10, but more than 1 person in 100):

- Taste disturbance

Very rare (affects less than 1 person in 10,000):

- Decreased vitamin B12 levels
- Skin rashes including redness, itching and hives.

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 METSAFE ER

Keep METSAFE ER tablets out of the reach and sight of children.

Do not use them after the expiry date that is printed on the pack after “Use before:”.

The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 the tablets contain

Each extended release tablet contains 500 or 1000 milligrams of the active ingredient Metformin Hydrochloride.

The other ingredients are microcrystalline cellulose, povidone K 90, Hydroxypropyl Methylcellulose (Methocel K100M), Colloidal silicon dioxide and magnesium stearate.

The 500 mg Tablets are white to off white colored, oval shaped, biconvex uncoated tablets with plain surface on both sides.

The 1000 mg Tablets are white to off white colored, oval shaped, biconvex, uncoated tablets debossed with 1000 on one side and plain surface on other side.

Tablets are provided in blister packs (PVC/PVdC blister pack).

This leaflet was last revised in 02/2014.

Useful tips

- If you smoke, try to stop
- Take regular exercise
- Drink as little alcohol as possible
- Look after your feet. Ask about this at the surgery or hospital
- Carry a card, bracelet or disk saying you are diabetic
- Visit your diabetic clinic regularly

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