Package leaflet: Information for the user

Metformin 500 mg film-coated tablets
Metformin 850 mg film-coated tablets
Metformin 1000 mg film-coated tablets
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 you . Do not pass it on to others. It may harm them, even if their symptoms 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

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1. What Metformin film-coated tablets are and what it is used for

Metformin film-coated tablets 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. Metformin film-coated tablets helps to lower your blood glucose to as normal a level as possible.

If you are an overweight adult, taking this medicine over a long period of time also helps to lower the risk of complications associated with diabetes. Metformin film-coated tablets is associated with either a stable body weight or modest weight loss.

Metformin film-coated tablets 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 metformin film-coated tablets 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 metformin film-coated tablets on its own or together with insulin.

2. What you need to know before you take Metformin film-coated tablets

Do not take Metformin film-coated tablets :

- if you are allergic(hypersensitive)to metformin or any of the other ingredients of this medicine (listed in section 6).
- if you have liver problems.
- if you have severely reduced kidney function.
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
- 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').
- if you have a severe infection, such as an infection affecting your lungs 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 are treated for acute 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').
- 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 this medicine for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment during this time. It is important that you follow your doctor's instructions precisely.

Warnings and precautions

Risk of lactic acidosis
Metformin film-coated tablets may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).

- If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Metformin film-coated tablets for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Metformin film-coated tablets and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.
Symptoms of lactic acidosis include:

- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat.

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor promptly for further instructions if:.

- you are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).

- you have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness

If you need to have major surgery you must stop taking this medicine during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Metformin film-coated tablets .

Metformin film-coated tablets on its own does not cause hypoglycaemia (a blood glucose level which is too low). However, if you take Metformin film-coated tablets together with other medicines to treat diabetes (such as sulphonylureas, insulin or 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.

During treatment with this medicine, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

Other medicines and Metformin film-coated tablets

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Metformin film-coated tablets before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with Metformin film-coated tablets .
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests or your doctor may need to adjust the dosage of Metformin film-coated tabletsIt is especially important to mention the following:

- medicines which increase urine production (diuretics).
- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- 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).

- medicines that may change the amount of metformin in your blood, especially if you have reduced kidney function (such asverapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprime, vandetanib, isavuconazole, crizotinib, olaparib).
- other medicines used to treat diabetes.

Metformin film-coated tablets with alcohol
Avoid excessive alcohol intake while taking Metformin film-coated tablets since this may increase the risk of lactic acidosis (see section 'Warnings and precautions').

Pregnancy and breast-feeding
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 film-coated tablets 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 film-coated tablets 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 Metformin film-coated tablets

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

Metformin film-coated tablets 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.

Recommended dose

Children 10 years and over and adolescents usually start with 500 mg or 850 mg Metformin film-coated tablets 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.

Adults usually start with 500 mg or 850 mg Metformin film-coated tablets two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses.

If you have reduced kidney function, your doctor may prescribe a lower dose.

If you take insulin too, your doctor will tell you how to take Metformin film-coated tablets .

Monitoring
- Your doctor will perform regular blood glucose tests and will adapt your dose of metformin 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 take **Metformin film-coated tablets:**

Take this medicine during 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 this medicine is too strong or too weak, talk to your doctor or pharmacist.

If you take more Metformin film-coated tablets than you should

If you have taken more medicine than you should have, you may experience lactic acidosis.
Symptoms of lactic acidosis are 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 heartbeat.
If you experience some of these symptoms, you should seek immediately medical attention, as lactic acidosis may lead to coma. Stop taking Metformin film-coated tablets immediately and contact a doctor or the nearest hospital straight away.

If you forget to take Metformin film-coated tablets
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:

Metformin film-coated tablets may cause a very rare (may affect up to 1 in 10,000 people), but very serious side effect called lactic acidosis (see section 'Warnings and precautions'). If this happens you must **stop taking Metformin film-coated tablets and contact a doctor or the nearest hospital immediately,** as lactic acidosis may lead to coma.

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 film coated tablets. It helps if you spread the doses over the day and if you take this medicine with or straight after a meal. **If symptoms continue, stop taking Metformin film-coated tablets and talk to your doctor.**

Common side effects (may affect up to 1 in 10 people)

- changes in taste.
- 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 side effects (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 non-specific (see section 'Warning and precautions').
- 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 Metformin film-coated tablets and talk to your doctor.**
- skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metformin film-coated tablets

Keep this medicine out of the sight and reach of children. If a child is treated with Metformin film-coated tablets, parents and caregivers are advised to oversee how this medicine is used.This medicine does not require any special storage conditions. Do not use this medicine after the expiry date which is stated on the carton or the bottle or the blister after 'EXP'. The expiry date refers to the last day of that month.Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Metformin film-coated tablets contains
The active substance is metformin hydrochloride.

One film-coated tablet of Metformin 500 mg contains 500 mg metformin hydrochloride corresponding to 390 mg metformin base.

One film-coated tablet of Metformin 850 mg contains 850 mg metformin hydrochloride corresponding to 662.9 mg metformin base.

One film-coated tablet of Metformin 1000 mg contains 1000 mg metformin hydrochloride corresponding to 780 mg metformin base

-The other ingredients are: Sodium Starch Glycolate (Type A), povidone K-30, Maize Starch, Colloidal Anhydrous Silica, Magnesium stearate, Isopropyl alcohol, hypromellose, Titanium dioxide E171, Purified Talc, Macrogol – 6000, Propylene glycol.

What Metformin film-coated tablets looks like and contents of the pack
Metformin 500 mg film-coated tablets are white, round 11.00 mm, biconvex film-coated tablets debossed with ‘500’ on one face and plain on the other.

Metformin 850 mg film-coated tablets are white, round 13.50 mm, biconvex film-coated tablets debossed with ‘850’ on one face and plain on the other.

Metformin 1000 mg film-coated tablets are white to off-white oval shaped 19.00 mm x 10.50 mm , biconvex, film-coated tablets debossed with ‘10’ and 00 on either side of deep notch on one side and breakline on the other side.

Metformin 500 mg film-coated tablets are supplied in Clear PVC/PVDC/Aluminium blister of 14 tablets. Pack size: 14, 28, 56 or 84 tablets.

Metformin 500 mg film-coated tablets are supplied in HDPE bottle. Pack size: 100, 105, 112, 336, 400and 1000 tablets.

Metformin 850 mg film-coated tablets are supplied in Clear PVC/PVDC/Aluminium blister of 14 tablets. Pack size: 14, 28, 56 or 84 tablets.

Metformin 850 mg film-coated tablets are supplied in HDPE bottle. Pack size: 250 and 500 tablets.

Metformin 1000 mg film-coated tablets are supplied in Clear PVC/PVDC/Aluminium blister of 14 tablets. Pack size: 14, 28, 56 or 84 tablets.

Metformin 1000 mg film-coated tablets are supplied in HDPE bottle. Pack size: 30, 63, 210 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Ipca Laboratories UK Ltd.,
Unit 97-98, Silverbriar,
Sunderland Enterprise Park East,
Sunderland, SR5 2TQ,
United Kingdom
Telephone: +44 (0) 1915166517
Fax: +44 (0) 1915166526
Email: regulatoryfrm.mumbai@ipca.com

Manufacturer:
Elara Pharmaservices Limited
Iron Farm,
7 Grimes Gates,
Diseworth,
DE74 2QD,
United Kingdom

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