Metformin Film-coated Tablets Leaflet

Front

150 mm 10 mm 10 mm Package Leaflet: Information for the user Risk of lactic acidosis Pharma Code 3081 Metformin Film-coated Tablets may cause a very **Metformin 500mg** rare, but very serious side effect called lactic **Film-coated Tablets** acidosis, particularly if your kidneys are not Metformin 850mg working properly. The risk of developing lactic acidosis is also increased with uncontrolled Film-coated Tablets diabetes, serious infections, prolonged fasting Metformin 1000mg or alcohol intake, dehydration, liver problems Film-coated Tablets and any medical conditions in which a part of Metformin Hydrochloride the body has a reduced supply of oxygen (such as acute severe heart disease). Read all of this leaflet carefully before If any of the above apply to you, talk to your you start taking this medicine because it doctor for further instructions. contains important information for you. **Stop taking Metformin Film-coated Tablets for** a short time if you have a condition that may • Keep this leaflet. You may need to read it again. be associated with dehydration (significant loss • If you have any further questions, ask your of body fluids) such as severe vomiting, diarrhoea, doctor or pharmacist. fever, exposure to heat or if you drink less fluid • This medicine has been prescribed for you than normal. Talk to your doctor for further only. Do not pass it on to others. It may harm instructions. them, even if their signs of illness are the **Stop taking Metformin Film-coated Tablets** same as yours. and contact a doctor or the nearest hospital If you get any side effects, talk to your doctor immediately if you experience some of the or pharmacist. This includes any possible side symptoms of lactic acidosis, as this condition effects not listed in this leaflet. See section 4. may lead to coma. What is in this leaflet: Symptoms of lactic acidosis include: 1. What Metformin Film-coated Tablets are • vomiting • stomach ache (abdominal pain) and what they are used for 2. What you need to know before you take muscle cramps • a general feeling of not being well with Metformin Film-coated Tablets severe tiredness 3. How to take Metformin Film-coated Tablets • difficulty in breathing 4. Possible side effects • reduced body temperature and heartbeat. 5. How to store Metformin Film-coated Tablets Lactic acidosis is a medical emergency and 6. Contents of the pack and other information must be treated in a hospital. 1. What Metformin Film-coated Tablets are If you need to have major surgery you must and what they are used for stop taking this medicine during and for some time after the procedure. Your doctor will decide Metformin Film-coated Tablets contains when you must stop and when to restart your metformin, a medicine to treat diabetes. treatment with Metformin Film-coated Tablets. It belongs to a group of medicines called Metformin Film-coated Tablets on its own do biguanides. not cause hypoglycaemia (a blood glucose level Metformin Film-coated Tablets are used to which is too low). However, if you take Metformin treat patients with type 2 diabetes (also called Film-coated Tablets together with other medicines 'non-insulin dependent diabetes') when diet to treat diabetes (such as sulphonylure as, insulin and exercise alone have not been enough to or meglitinides) there is a risk of hypoglycaemia. control your blood glucose levels. It is used If you experience symptoms of hypoglycaemia particularly in overweight patients. Insulin is such as weakness, dizziness, increased sweating, a hormone produced by the pancreas that fast heart beating, vision disorders or difficulty makes your body take in glucose (sugar) from in concentration, it usually helps to eat or drink the blood. Your body uses glucose to produce something containing sugar. energy or stores it for future use. During treatment with this medicine, your doctor If you have diabetes, your pancreas does not will check your kidney function at least once a make enough insulin or your body is not able year or more frequently if you are elderly and/or to use properly the insulin it produces. This if you have worsening kidney function. leads to a high level of glucose in your blood. **Children and adolescents** Metformin Film-coated Tablets help to lower Treatment of children between 10 and 12 years your blood glucose to as normal a level as of age is only recommended on specific advice from your doctor, as experience in this age group If you are an overweight adult, taking this is limited (see section 3 "Use in children and medicine over a long period of time also helps adolescents"). to lower the risk of complications associated Other medicines and Metformin Film-coated with diabetes. **Tablets** Metformin is associated with either a stable Tell your doctor or pharmacist if you are taking, body weight or modest weight loss. have recently taken or might take any other Adults can take metformin on its own or together medicines. You may need more frequent blood with other medicines to treat diabetes (medicines glucose and kidney function tests or your doctor taken by mouth or insulin). may need to adjust the dosage of Metformin Film-coated Tablets. Children 10 years and over and adolescents can If you need to have an injection of a contrast take metformin on its own or together with medium that contains iodine into your bloodstream, for example in the context of an 2. What you need to know before you take Xray or scan, you must stop taking Metformin **Metformin Film-coated Tablets** Film-coated Tablets before or at the time of Do not take Metformin Film-coated Tablets: injection. Your doctor will decide when you must stop and when to restart your treatment • if you are allergic to metformin or any of the other ingredients of this medicine (listed in with Metformin Film-coated Tablets. section 6). It is especially important to mention to your doctor if you are taking: • if you have liver problems. • medicines which increase urine production • if you have severely reduced kidney function. (diuretics). • if you have uncontrolled diabetes, with, for medicines used to treat pain and inflammation example, severe hyperglycaemia (high blood (NSAID and COX-2-inhibitors, such as ibuprofen glucose), nausea, vomiting, diarrhoea, rapid and celecoxib). weight loss, lactic acidosis (see "Risk of lactic • certain medicines for the treatment of high acidosis" below) or ketoacidosis. Ketoacidosis blood pressure (ACE inhibitors and angiotensin is a condition in which substances called 'ketone Il receptor antagonists). bodies' accumulate in the blood and which • beta-2 agonists such as salbutamol or can lead to diabetic pre-coma. Symptoms terbutaline (used to treat asthma). include stomach pain, fast and deep breathing, corticosteroids (used to treat a variety of sleepiness or your breath developing an conditions, such as severe inflammation unusual fruity smell. of the skin or in asthma). • if you lost too much water from your body • medicines that may change the amount of (dehydration), due to long-lasting or severe metformin in your blood, especially if you diarrhoea, or if you have vomited several have reduced kidney function (such as verapamil, times in a row. Dehydration may lead to rifampicin, cimetidine, dolutegravir, ranolazine, kidney problems, which can put you at risk trimethoprime, vandetanib, isavuconazole, for lactic acidosis (see 'Warnings and crizotinib, olaparib). precautions'). • other medicines used to treat diabetes. • if you have a severe infection, such as an **Metformin Film-coated Tablets with alcohol** infection affecting your lungs or bronchial Avoid excessive alcohol intake while taking system or your kidney. Severe infections Metformin Film-coated Tablets since this may may lead to kidney problems, which can increase the risk of lactic acidosis (see section put you at risk for lactic acidosis (see 'Warnings 'Warnings and precautions'). and precautions'). Pregnancy and breast-feeding • if you are treated for acute heart failure or If you are pregnant or breast-feeding, think you have recently had a heart attack, have severe may be pregnant or are planning to have a baby, problems with your circulation (such as shock) ask your doctor or pharmacist for advice before or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put

> doctor before you start taking this medicine. Make sure you ask your doctor for advice if: • you need to have an examination such as

> If any of the above applies to you, talk to your

you at risk for lactic acidosis (see 'Warnings and

- Xray or scan involving the injection of contrast medicines that contain iodine into your blood
- you need to have major surgery.

precautions').

• if you drink a lot of alcohol.

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

Talk to your doctor or pharmacist before taking Metformin Film-coated Tablets.

taking this medicine.

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.

This medicine is not recommended if you are breast-feeding or if you are planning to

breastfeed your baby. **Driving and using machines**

Metformin Film-coated Tablets on its own do 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 hypogrycal dizziness, increased sweating, fast hear weak, vision disorders or difficulty in concentration.

The drive or use machines if you start to

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Front

Artwork Size: 150 x 480 mm **Country:** United Kingdom Item Code: IIXXN2 **Text Area:** 130 x 470 mm



Metformin Film-coated Tablets Leaflet

Back

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150 mm 10 mm 3. How to take Metformin Film-coated Tablets Additional side effects in children and Always take this medicine exactly as your doctor adolescents or pharmacist has told you. Check with your doctor Limited data in children and adolescents showed or pharmacist if you are not sure. Metformin Filmthat adverse events were similar in nature and coated Tablets cannot replace the benefits of a severity to those reported in adults. healthy lifestyle. Continue to follow any advice about diet that your doctor has given you and get some regular exercise. **Reporting of side effects** If you get any side effects, talk to your doctor or The recommended dose is: pharmacist. This includes any possible side effects Adults usually start with 500 mg or 850 mg not listed in this leaflet. You can also report side Metformin Film-coated Tablets two or three effects directly via the Yellow Card Scheme at times a day. The maximum daily dose is 3000 mg www.mhra.gov.uk/yellowcard or search for taken as 3 divided doses. If you have reduced MHRA Yellow Card in the Google Play or Apple kidney function, your doctor may prescribe a App Store. By reporting side effects you can help provide If you take insulin too, your doctor will tell you more information on the safety of this medicine. how to take Metformin Film-coated Tablets. Use in children and adolescents 5. How to store Metformin Film-coated Tablets Children 10 years and over and adolescents usually start with 500 mg or 850 mg Metformin Keep this medicine out of the sight and reach Film-coated Tablets once a day. The maximum of children. If a child is treated with Metformin daily dose is 2000 mg taken as 2 or 3 divided Film-coated Tablets, parents and caregivers are advised to oversee how this medicine is taken. Treatment of children between 10 and 12 years This medicine does not require any special of age is only recommended on specific advice storage conditions. Do not use this medicine from your doctor, as experience in this age after the expiry date which is stated on the group is limited. carton or the bottle or the blister after 'EXP'. The expiry date refers to the last day of that Monitoring month. Do not throw any medicines via waste • Your doctor will perform regular blood glucose water or household waste. Ask your pharmacist tests and will adapt your dose of metformin to how to throw away medicines you no longer your blood glucose levels. Make sure that you use. These measures will help to protect the talk to your doctor regularly. This is particularly environment. important for children and adolescents or if you are an older person. 6. Contents of the pack and other information Your doctor will also check at least once a What Metformin Film-coated Tablets contain yearhow well your kidneys work. You may need more frequent checks if you are an The active substance is metformin hydrochloride. older person or if your kidneys are not One film-coated tablet of Metformin 500 mg working normally. contains 500 mg metformin hydrochloride corresponding to 390 mg metformin base. **Taking Metformin Film-coated Tablets:** One film-coated tablet of Metformin 850 mg Take this medicine during or after a meal. This contains 850 mg metformin hydrochloride will avoid you having side effects affecting your corresponding to 662.9 mg metformin base. One film-coated tablet of Metformin 1000 mg Do not crush or chew the tablets. Swallow each tablet with a glass of water. contains 1000 mg metformin nydrochioride corresponding to 780 mg metformin base. If you take one dose a day, take it in the morning (breakfast). - The other ingredients are: Sodium Starch • If you take two divided doses a day, take them Glycolate (Type A), povidone K-30, Maize in the morning (breakfast) and evening (dinner). Starch, Colloidal Anhydrous Silica, Magnesium • If you take three divided doses a day, take stearate, Isopropyl alcohol, hypromellose, them in the morning (breakfast), at noon Titanium dioxide E171, Purified Talc, (lunch) and in the evening (dinner). Macrogol – 6000, Propylene glycol. If, after some time, you think that the effect of this medicine is too strong or too weak, talk to What Metformin Film-coated Tablets look like your doctor or pharmacist. and contents of the pack If you take more Metformin Film-coated Metformin 500 mg Film-coated Tablets are white, Tablets than you should round 11.00 mm, biconvex film-coated tablets If you have taken more medicine than you debossed with '500' on one face and plain on should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific Metformin 850 mg Film-coated Tablets are white, such as vomiting, bellyache (abdominal pain) round 13.50 mm, biconvex film-coated tablets 480 mm with muscle cramps, a general feeling of not debossed with '850' on one face and plain on being well with severe tiredness and difficulty the other. in breathing. Further symptoms are reduced Metformin 1000 mg Film-coated Tablets are body temperature and heartbeat. white to off-white, oval shaped 19.00 mm x 10.50 mm, biconvex film-coated tablets If you experience some of these symptoms, debossed with '10' and '00' on either side of you should seek immediate medical attention, deep notch on one side and breakline on the as lactic acidosis may lead to coma. Stop taking other side. **Metformin Film-coated Tablets immediately** Metformin 500 mg Film-coated Tablets are and contact a doctor or the nearest hospital supplied in Clear PVC/PVDC/Aluminium blister straight away. of 14 tablets. Pack size: 14, 28, 56 or 84 tablets. If you forget to take Metformin Film-coated Metformin 500 mg Film-coated Tablets are **Tablets** supplied in HDPE bottle. Pack size: 100, 105, 112, 336, 400 and 1000 tablets. Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual Metformin 850 mg Film-coated Tablets are supplied in Clear PVC/PVDC/Aluminium blister If you have any further questions on the use of of 14 tablets. Pack size: 14, 28, 56 or 84 tablets. this medicine, ask your doctor or pharmacist. Metformin 850 mg Film-coated Tablets are supplied in HDPE bottle. Pack size: 250 and 4. Possible side effects 500 tablets. Like all medicines, this medicine can cause side Metformin 1000 mg Film-coated Tablets are effects, although not everybody gets them. supplied in Clear PVC/PVDC/Aluminium blister Metformin Film-coated Tablets may cause a very of 14 tablets. Pack size: 14, 28, 56 or 84 tablets. rare (may affect up to 1 in 10,000 people), but Metformin 1000 mg Film-coated Tablets are very serious side effect called lactic acidosis supplied in HDPE bottle. Pack size: 30, 63, 210 (see section 'Warnings and precautions'). If this and 1000 tablets. happens you must stop taking Metformin Film-coated Tablets and contact a doctor or the nearest hospital immediately, as lactic Not all pack sizes may be marketed. acidosis may lead to coma Other side effects which may occur: **Marketing Authorisation Holder** Very common (may affect more than 1 in 10 and Manufacturer: people) digestive problems such as feeling sick **Marketing Authorisation Holder** (nausea), being sick (vomiting), diarrhoea, bellyache (abdominal pain) and loss of **%**ipca **Ipca Laboratories UK Ltd.** These side effects most often happen at the Unit 97-98, Silverbriar, beginning of the treatment with metformin. Sunderland Enterprise Park East, It helps if you spread the doses over the day and if you take this medicine with or straight Sunderland, SR5 2TQ, after a meal. If symptoms continue, stop **United Kingdom** taking Metformin Film-coated Tablets and Telephone: +44 (0) 1915166517 talk to your doctor. Fax: +44 (0) 1915166526 **Common** (may affect up to 1 in 10 people) Email: regulatoryfrm.mumbai@ipca.com • changes in taste.

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Back

and precautions').

your doctor.

Very rare (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

• 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**

skin reactions such as redness of the skin (erythema), itching or an itchy rash (hives).
low vitamin B₁₂ levels in the blood. Manufacturer

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