

Metformin Film-coated Tablets

Leaflet

Front



Artwork Size: 150 x 480 mm

Country: United Kingdom

Item Code: IIXXN2

Text Area: 130 x 470 mm

BLACK



Pharma Code 3081

Metformin Film-coated Tablets

Leaflet

Back

150 mm

10 mm | 10 mm

5 mm

3. How to take Metformin Film-coated Tablets

Always take this medicine exactly as your doctor or pharmacist 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.

The recommended dose is:

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.

Use in children and adolescents

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.

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.

Taking 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 immediate 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. 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.

Other side effects which may occur:

Very common (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. 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 (may affect up to 1 in 10 people)

- changes in taste.

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 'Warnings 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).
- low vitamin B₁₂ levels in the blood.

Additional side effects in 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 taken. 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 waste water 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 contain

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 look 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, 400 and 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:

Marketing Authorisation Holder

 ipca

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 Pharmservices Limited

7 Grimes Gate,
Diseworth,
DE74 2QD,
UK

This leaflet was last revised in 05/2021

IIXXN2

480 mm

5 mm

Back

Artwork Size: 150 x 480 mm