

PACKAGE LEAFLET: INFORMATION FOR THE USER

Competact 15 mg/850 mg film-coated tablets Pioglitazone/Metformin hydrochloride

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.

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1. What Competact is and what it is used for
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1. WHAT COMPETACT IS AND WHAT IT IS USED FOR

Competact contains pioglitazone and metformin. It is an anti-diabetic medicine used in adults to treat type 2 (non-insulin dependent) diabetes mellitus when treatment with metformin alone is not sufficient. This type 2 diabetes usually develops in adulthood particularly as a result of the person being overweight and where the body either does not produce enough insulin (a hormone that controls blood sugar levels), or cannot effectively use the insulin it produces. Your doctor will check whether Competact is working 3 to 6 months after you start taking it.

Competact helps control the level of sugar in your blood when you have type 2 diabetes by helping your body make better use of the insulin it produces.

2. BEFORE YOU TAKE COMPETACT

Do not take Competact

- if you are allergic (hypersensitive) to pioglitazone, metformin or any of the other ingredients of Competact.
- if you have heart failure or have had heart failure in the past.
- if you recently had a heart attack, have severe circulatory problems including shock, or breathing difficulties.
- if you have liver disease.
- if you drink alcohol excessively (either every day or only from time to time).
- if you have diabetic ketoacidosis (a complication of diabetes with rapid weight loss, nausea or vomiting).
- if you have or have ever had bladder cancer.
- if you have blood in your urine that your doctor has not checked.
- if you have a problem with your kidneys.
- if you have a severe infection or are dehydrated.
- if you are going to have a certain type of X-ray with an injectable dye. You will need to stop taking Competact at the time of and for a few days after the procedure.
- if you are breast-feeding.

Take special care with Competact

Tell your doctor before you start to take this medicine

- if you have a problem with your heart. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin together experienced the development of heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).
- if you retain water (fluid retention) or have heart failure problems in particular if you are over 75 years old. If you take anti-inflammatory medicines which can also cause fluid retention and swelling, you must also tell your doctor.
- if you have a special type of diabetic eye disease called macular oedema (swelling of the back of the eye).
- if you are going to have an operation under general anaesthetic, as you may need to stop taking Competact for a couple of days before and after the procedure.
- if you have cysts on your ovaries (polycystic ovary syndrome). There may be an increased possibility of becoming pregnant because you may ovulate again when you take Competact. If this applies to you, use appropriate contraception to avoid the possibility of an unplanned pregnancy.
- if you have a problem with your liver. Before you start taking Competact you will have a blood sample taken to check your liver function. This check should be repeated at intervals. Inform your doctor as soon as possible if you develop symptoms suggesting a problem with your liver (like feeling sick without explanations, vomiting, abdominal pain, tiredness, loss of appetite and/or dark urine) as your liver function should be checked.

If you take Competact with other medicines for diabetes, it is more likely that your blood sugar could fall below the normal level (hypoglycaemia).

You may also experience a reduction in blood count (anaemia).

Broken bones

A higher number of bone fractures was seen in patients, particularly women taking pioglitazone. Your doctor will take this into account when treating your diabetes.

Children

Use in children under 18 years is not recommended.

Taking other medicines

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

Certain medicines are especially likely to affect the amount of sugar in your blood:

- gemfibrozil (used to lower cholesterol)
- rifampicin (used to treat tuberculosis and other infections)
- cimetidine (used to reduce stomach acid)
- glucocorticoids (used to treat inflammation)
- beta-2-agonists (used to treat asthma)
- diuretics (used to get rid of excess water)
- angiotensin-converting enzyme (ACE) inhibitors (used to treat high blood pressure)

Tell your doctor or pharmacist if you are taking any of these. Your blood sugar will be checked, and your dose of Competact may need to be changed.

Taking Competact with food and drink

You may take your tablets with or just after food to reduce the chance of an upset stomach.

Avoid alcohol or medicines containing alcohol while taking Competact since alcohol may increase the risk of lactic acidosis (please see section “Possible side effects”).

Pregnancy and breast-feeding

- you must tell your doctor if you are, you think you might be or are planning to become pregnant. Competact is not recommended in pregnancy. Your doctor will advise you to discontinue this medicine.
- do not use Competact if you are breastfeeding or are planning to breast-feed.

Driving and using machines

This medicine will not affect your ability to drive or use machines but take care if you experience abnormal vision.

3. HOW TO TAKE COMPETACT

Always take Competact exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one tablet taken twice daily. If necessary your doctor may tell you to take a different dose. You should swallow the tablets with a glass of water. You may take your tablets with or just after food to reduce the chance of an upset stomach.

If you are following a diabetic diet, you should continue with this while you are taking Competact.

Your weight should be checked at regular intervals; if your weight increases, inform your doctor.

Your doctor will ask you to have blood tests periodically during treatment with Competact. This is to check that your liver is working normally. At least once a year (more often if you are elderly or have kidney problems) your doctor will check that your kidneys are working normally.

If you take more Competact than you should

If you accidentally take too many tablets, or if someone else or a child takes your medicine, talk to a doctor or pharmacist immediately. Your blood sugar could fall below the normal level and can be increased by taking sugar. It is recommended that you carry some sugar lumps, sweets, biscuits or sugary fruit juice.

If you forget to take Competact

Take Competact daily as prescribed. However if you miss a dose, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Competact

Competact should be used every day to work properly. If you stop using Competact, your blood sugar may go up. Talk to your doctor before stopping this treatment.

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

4. POSSIBLE SIDE EFFECTS

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

Very rarely patients taking metformin (one of the active substances of Competact) have experienced a condition called lactic acidosis (excess of lactic acid in your blood), particularly those whose kidneys are not working properly. Symptoms include feeling cold and uncomfortable, severe nausea and vomiting, abdominal pain, unexplained weight loss, or rapid breathing. **If you experience any of these symptoms, stop taking Competact and consult a doctor immediately.**

Bladder cancer has been experienced uncommonly (1 to 10 users in 1000) in patients taking Competact. Signs and symptoms include blood in your urine, pain when urinating or a sudden need to urinate. If you experience any of these, talk to your doctor as soon as possible.

Blurred vision due to swelling (or fluid) at the back of the eye has been reported (frequency not known). If you experience these symptoms for the first time talk to your doctor as soon as possible. Also, if you already have blurred vision and the symptoms get worse, talk to your doctor as soon as possible.

Allergic reactions have been reported (frequency not known) in patients taking Competact. If you have a serious allergic reaction, including hives and swelling of the face, lips, tongue, or throat that may cause difficulty in breathing or swallowing stop taking this medicine and talk to your doctor as soon as possible.

The following side effects have been experienced by some patients taking Competact

Very common (affects more than 1 user in 10)

- abdominal pain
- feeling sick (nausea)
- vomiting
- diarrhoea
- loss of appetite

Common (affects 1 to 10 users in 100)

- localised swelling (oedema)
- weight gain
- headache
- respiratory infection
- abnormal vision
- joint pain
- impotence
- blood in urine
- reduction in blood count (anaemia)
- numbness
- taste disturbance
- bone fracture

Uncommon (affects 1 to 10 users in 1,000)

- inflammation of the sinuses (sinusitis)
- gas
- difficulty sleeping (insomnia)

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

- decrease in amount of vitamin B₁₂ in the blood
- lactic acidosis (excess of lactic acid in your blood)
- redness of the skin
- itchy skin
- raised and itchy rash (hives)

Not known (frequency can not be estimated from the available data)

- blurred vision due to swelling (or fluid) in the back of the eye
- inflammation of the liver (hepatitis)
- liver does not work as well as it should (changes in liver enzymes)
- allergic reactions

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 COMPETACT

Keep out of the reach and sight of children.

Do not use Competact after the expiry date which is stated on the carton and the blister pack after "EXP". The expiry date refers to the last day of that month.

This medicine 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 Competact contains

- The active substances are 15 mg pioglitazone (as hydrochloride) and 850 mg metformin hydrochloride.
- The other ingredients are microcrystalline cellulose, povidone (K 30), croscarmellose sodium magnesium stearate, hypromellose, macrogol 8000, talc and titanium dioxide.

What Competact looks like and contents of the pack

Competact tablets are white to off white, oblong, convex, film-coated tablets (tablets) embossed '15 / 850' on one face and '4833M' on the other. The tablets are supplied in aluminium/aluminium blister packs of 14, 28, 30, 50, 56, 60, 90, 98, 112, 180, 196 (2 x 98) tablets or 60 x 1 tablets in aluminium/aluminium perforated unit dose blisters.

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Marketing authorisation holder:

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Detailed information on this medicine is available on the European Medicines Agency website
<http://www.ema.europa.eu>