

Modalim® 100mg Tablets

(ciprofibrate)

Patient information leaflet

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 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.
- * Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect

Your medicine is called Modalim 100mg Tablets but will be referred to as Modalim throughout this leaflet.

In this leaflet:

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

1 What Modalim is and what it is used for

The name of your medicine is Modalim 100mg Tablets (called Modalim throughout this leaflet).

This belongs to a group of medicines commonly known as 'fibrates'. These medicines are used to lower the level of fats (lipids) in the blood.

For example the fats known as triglycerides.

Modalim is used alongside a low fat diet and other non-medical treatments such as exercise and weight loss, to lower levels of fats in the blood.

2 Before you take Modalim

Do not take Modalim if:

- * You are allergic (hypersensitive) to Modalim or any of the other ingredients of Modalim (see Section 6: Further information) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
 - * You are pregnant, might become pregnant or think you may be pregnant (see "Pregnancy and breast-feeding" section below)
 - * You are breast-feeding (see "Pregnancy and breast-feeding" section below)
 - * You have severe liver or kidney problems
 - * You are taking 'fibrates' (such as clofibrate, bezafibrate, fenofibrate or gemfibrozil)- used to treat high blood fat levels
- Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Modalim.

Take special care with Modalim.

Check with your doctor or pharmacist before taking Modalim if you:

- * have unexpected muscle pains, tenderness or weakness
- * have liver or kidney problems
- * have an under-active thyroid gland
- * are over 70 years of age
- * or a member of your family have had muscle problems in the past.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Modalim.

Blood Tests

- * Taking Modalim may affect the results of some blood tests. During treatment your doctor may do blood tests to check how your liver is working
- * If you are going to have any other blood tests, it is important to tell the person taking the test that you are taking Modalim.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because Modalim can affect the way some other medicines work. Also some medicines can affect the way Modalim works.

Tell your doctor if you are taking any of the following medicines:

- * Statins (such as simvastatin, atorvastatin, pravastatin, fluvastatin and rosuvastatin)- used to treat high blood fat levels
- * Warfarin - used for thinning the blood
- * Insulin or Metformin - used for diabetes
- * Contraceptive medicines (such as 'The Pill') or hormone replacement therapy (HRT)

Taking Modalim with alcohol

One of the side effects of this medicine is muscle problems. Drinking a lot of alcohol may increase the chance of muscle problems. This means that you must limit the amount of alcohol you drink while you are taking Modalim. Ask your doctor for more advice.

Pregnancy and breast-feeding

Do not take Modalim if you are:

- * Pregnant, might become pregnant, or think you may be pregnant
- * Breast-feeding or planning to breast-feed.

This is because small amounts of Modalim may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

If you get dizzy, drowsy and tired while taking Modalim, then you should not drive or use any tools or machinery.

Important information about some of the ingredients of Modalim

Modalim 100mg tablets contain lactose.

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium free'.

3 How to take Modalim

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

Taking this medicine

- * Take this medicine by mouth
- * Do not give to children under 12 years
- * It is important while you are taking Modalim to keep to any special diet you have been given
- * If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take

- * The usual dose for adults is 1 tablet every day
- * Do not take any more than 1 tablet each day
- * If you have kidney problems, only take 1 tablet **every other day**.

Modalim® 100mg Tablets

(ciprofibrate)

Patient information leaflet (continued)

If you take more Modalim than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Modalim

- * If you forget a dose, take it as soon as you remember it.
- * However, if it is time for the next dose, skip the missed dose.
- * Do not take a double dose to make up for a forgotten dose.

If you stop taking Modalim

Keep taking your medicine until your doctor tells you to stop. Do not stop taking Modalim just because you feel better. If you stop, your illness may get worse.

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

4 Possible side effects

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

Stop taking your medicine and see a doctor or go to a hospital straight away - you may need urgent medical treatment.

- * Muscle problems, such as cramps, pain or tenderness. This can lead to kidney failure.

Tell your doctor as soon as possible if you have any of the following side effects:

- * An allergic reaction. The signs may include: a rash (which may be itchy and lumpy), itching and being more sensitive to the sun than usual.
- * Inflammation of the lungs which causes breathlessness, cough and raised temperature.
- * Scarring of the lungs which causes shortness of breath.
- * Liver problems. This may cause the eyes or skin to go yellow (jaundice).
- * Severe pain in the upper right corner of your stomach, which could reach through to your back.

You may also have a fever and feel or be sick. This could be a sign of biliary colic or gallstones.

Other side effects are:

Common (may affect up to 1 in 10 people):

- * Hair loss, balding.
- * Headache, balance problems.
- * Feeling dizzy, drowsy or tired.
- * Feeling sick (nausea) or being sick (vomiting).
- * Diarrhoea, indigestion or stomach pains.
- * Pain in your muscles.

Not Known (frequency cannot be estimated from the available data):

- * Impotence
- * You may bruise more easily than usual.
This could be because of a blood disorder (thrombocytopenia).
- * Muscle weakness, cramps, stiffness and spasm.
- * Inflammation of your muscles.

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 Modalim

- * KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- * Do not store above 25°C.
- * Store in the original package.
- * Do not use Modalim after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- * If the tablet becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- * Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6 Further information

What Modalim contains

Each tablet contains 100mg of ciprofibrate as the active ingredient. Modalim also contains the following inactive ingredients: sterotex K, maize starch, lactose, microcrystalline cellulose, methylhydroxypropylcellulose and sodium lauryl sulphate.

What Modalim looks like and contents of the pack

Modalim are white round tablets engraved with S170 on one side and a scoreline on the other side.

Modalim comes in packs of 28 tablets.

Manufacturer and Licence Holder:

Manufactured by Opella Healthcare Poland Sp. z.o.o., Oddział w Rzeszowie, Ul. Lubelska 52, 25-233 Rzeszów, Poland and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL: 15184/1193 Modalim 100mg Tablets

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Modalim is a registered trademark of Sanofi.

Revision date: 10/04/25

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Your medicine is called Ciprofibrate 100mg Tablets but will be referred to as Ciprofibrate throughout this leaflet.

In this leaflet:

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

1 What Ciprofibrate is and what it is used for

The name of your medicine is Ciprofibrate 100mg Tablets (called Ciprofibrate throughout this leaflet).

This belongs to a group of medicines commonly known as 'fibrates'. These medicines are used to lower the level of fats (lipids) in the blood.

For example the fats known as triglycerides.

Ciprofibrate is used alongside a low fat diet and other non-medical treatments such as exercise and weight loss, to lower levels of fats in the blood.

2 Before you take Ciprofibrate

Do not take Ciprofibrate if:

- * You are allergic (hypersensitive) to Ciprofibrate or any of the other ingredients of Ciprofibrate (see Section 6: Further information) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- * You are pregnant, might become pregnant or think you may be pregnant (see "Pregnancy and breast-feeding" section below)
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- * You have severe liver or kidney problems
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Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ciprofibrate.

Take special care with Ciprofibrate.

Check with your doctor or pharmacist before taking Ciprofibrate if you:

- * have unexpected muscle pains, tenderness or weakness
- * have liver or kidney problems
- * have an under-active thyroid gland
- * are over 70 years of age
- * or a member of your family have had muscle problems in the past.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Ciprofibrate.

Blood Tests

- * Taking Ciprofibrate may affect the results of some blood tests. During treatment your doctor may do blood tests to check how your liver is working
- * If you are going to have any other blood tests, it is important to tell the person taking the test that you are taking Ciprofibrate.

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Ciprofibrate 100mg Tablets

Patient information leaflet (continued)

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