

# Modalim® 100mg Tablets

## Ciprofibrate 100mg Tablets

(ciprofibrate)

Your medicine is known by one of the above names, but will be referred to as Ciprofibrate throughout this:

### 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 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
- 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

#### 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

Ciprofibrate 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)
- 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 Ciprofibrate.

#### Take special care with Ciprofibrate Check with your doctor or pharmacist before taking Ciprofibrate if:

- You have unexpected muscle pains, tenderness or weakness
- You have liver or kidney problems

- You have an under-active thyroid gland
  - You are over 70 years of age
  - You 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

#### 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 Ciprofibrate can affect the way some other medicines work. Also some medicines can affect the way Ciprofibrate 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 Ciprofibrate 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 Ciprofibrate. Ask your doctor for more advice.

#### Pregnancy and breast-feeding

Do not take Ciprofibrate 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 Ciprofibrate 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 Ciprofibrate, then you should not drive or use any tools or machinery.

#### Important information about some of the ingredients of Ciprofibrate

If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking Ciprofibrate.

### 3) How to take Ciprofibrate

Always take Ciprofibrate 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 Ciprofibrate 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

### If you take more Ciprofibrate 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 Ciprofibrate

- 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 Ciprofibrate

Keep taking your medicine until your doctor tells you to stop. Do not stop taking Ciprofibrate 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, Ciprofibrate 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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

### 5) How to store Ciprofibrate

- Keep all medicines out of the reach and sight of children.
- Do not use Ciprofibrate after the expiry date printed on the carton, and blister label. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- If the tablets become discoloured or show 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 no longer required. These measures will help to protect the environment.

### 6) Further information

#### What Ciprofibrate contains:

Each tablet contains 100mg of ciprofibrate as the active ingredient.

The other ingredients are maize starch, lactose, microcrystalline cellulose, methylhydroxypropylcellulose, stertex K and sodium lauryl sulphate.

#### What Ciprofibrate looks like and content of the pack

Ciprofibrate tablets are white, round tablets with a breakline on one side and 'S170' stamped on the other.

Ciprofibrate comes in blister packs of 28 tablets.

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**POM**

#### Who makes and repackages your medicine

Your medicine is manufactured by Sanofi-Aventis Sp. z o.o., Ul. Lubelska 52, 35-233 Rzeszów, Poland or Opella Healthcare Poland Sp. z o.o., Oddział w Rzeszowie, Ul. Lubelska 52, 35-233 Rzeszów, Poland. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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