PACKAGE LEAFLET: INFORMATION FOR THE USER Ciprofibrate 100mg Tablets

- Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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.

What is in this leaflet

- 1. What Ciprofibrate is and what it is used for
- 2. What you need to know before you take Ciprofibrate
- 3. How to take Ciprofibrate
- 4. Possible side effects
- 5. How to store Ciprofibrate
- 6. Contents of the pack and other 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). It contains a medicine called ciprofibrate. This belongs to a group of medicines called '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. What you need to know before you take Ciprofibrate

Do not take Ciprofibrate:

- if you are allergic to ciprofibrate or any of the other ingredients of this medicine (listed in section 6) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have previously taken ciprofibrate (or related substances) and your skin reacted badly to sunlight
- if you are pregnant, might become pregnant or think you may be pregnant (see "Pregnancy and breast-feeding" section below)
- if you are breast-feeding (see "Pregnancy and breast-feeding" section below)
- if you have severe liver or kidney problems
- if you are taking another fibrate (such as clofibrate, bezafibrate, fenofibrate or gemfibrozil) to treat high blood fat levels

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking ciprofibrate.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ciprofibrate if:

- you have unexpected muscle pains, tenderness or weakness.

The risk of muscle problems may be increased if you experience any of the following risk factors:

• you have kidney problems or a reduced amount of a protein (albumin) in the blood, such as when a particular disorder affecting the kidneys occurs (nephrotic syndrome)

- you have liver problems
- you have an under-active thyroid gland
- alcohol abuse
- age greater than 70 years
- personal or family history of hereditary muscular disorders
- previous history of muscular toxicity with another fibrate

If you are not sure if any of the above applies 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

Other medicines and Ciprofibrate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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
- Oral medicines used for thinning the blood, such as warfarin
- Oral medicines used for diabetes, such as metformin
- Medicines containing oestrogens, such as contraceptive medicines (such as "The Pill") or hormone replacement therapy (HRT)
- Medicines for treating epilepsy, such as phenytoin
- Other fibrates

Taking colestyramine or colestipol (other cholesterol-lowering drugs) at the same time can affect how well ciprofibrate works. These medicines should therefore not be taken at the same time or within a short time of each other.

Ciprofibrate with food, drink and 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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take ciprofibrate if you are pregnant and 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.

Ciprofibrate contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ciprofibrate.

3. How to take Ciprofibrate

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Do not give to children
- 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

The break line is only there to help you break the tablet if you have difficulty swallowing it whole.

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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), eczema, itching and being more sensitive to the sun than usual
- Feeling breathless. Some cases of pneumonia (pneumonitis) or increase of connective tissue in the lungs (pulmonary fibrosis) have been reported.
- 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:

Rare (may affect up to 1 in 1,000 people):

- Feeling dizzy, drowsy or tired

Not known (frequency cannot be estimated from the available data)

- Impotence
- Hair loss, balding

- You may bruise more easily than usual. This could be because of a blood disorder (decrease in platelets)
- A blood disorder that makes you more likely to have infections (decrease in white cells)
- Headache, balance problems
- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea, indigestion or stomach pains

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Ciprofibrate

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the blisters and carton after 'EXP'. The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original package to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ciprofibrate contains?

The active substance is ciprofibrate. Each tablet contains 100 mg ciprofibrate.

The other ingredients are lactose monohydrate, hydroxypropyl methyl cellulose, sodium lauril sulphate, purified water, microcrystalline cellulose, maize starch and powdered vegetable stearing/hydrogenated vegetable oil.

What Ciprofibrate Tablets look like and contents of the pack

Ciprofibrate 100mg tablets are white to off white capsule shaped tablets plain on one side and with a break line on the other side. The break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses. The tablets are supplied in blisters as a pack size of 28 tablets.

Marketing Authorisation Holder

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