

MODALIM[®] TABLET

Ciprofibrate 100 mg

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What Modalim is used for

Modalim is used to treat 'hyperlipidaemia' (high lipid/fat in the blood) when a patient does not respond well to low fat diet.

How Modalim works

Modalim contains an active ingredient called ciprofibrate. This belongs to a group of medicines called 'fibrates'. It works by lowering the amount of fat in your blood.

Before you use Modalim

When you must not use it

Do not take Modalim if:

- You are allergic (hypersensitive) to ciprofibrate or any of the other ingredients of Modalim. (see 8. Product Description)
- 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.
- You are breast-feeding or planning to breast feed. This is because small amounts of Modalim may pass into the mother's milk.
- You have severe liver or kidney problems.
- You are taking other fibrates medicine (such as clofibrate, bezafibrate, fenofibrate or gemfibrozil)- used 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 Modalim.

Before you start to use it

Talk to your doctor if:

- You have unexpected muscle pains, tenderness or weakness
- You have liver or kidney problems
- You have an under-active thyroid gland
- You are > 70 years

Important information about some of the ingredients of Modalim:

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

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before 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
- Oestrogen (hormone commonly found in contraceptive medicines or hormone replacement therapy-HRT)

How to use Modalim

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

How much to use

- 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.

When to use it

Modalim is to be taken orally and at the same time each day.

How long to use it

Continue taking your medicine for as long as your doctor continues to prescribe it.

Please talk to your doctor before you consider stopping treatment.

If you forget to use it

- 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 use too much (overdose)

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.

While you are using it

Things you must do

- Take this medicine by mouth
- 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.
- If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Blood Tests

- Taking Modalim may affect the results of some blood tests. If you are going to have any blood tests, it is

important to tell the person taking the test that you are taking Modalim.

- During treatment, your doctor may do blood tests to check how your liver is working.

Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as yours.
- Do not give this to children.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Modalim, or change the dosage, without checking with your doctor.
- Do not stop taking Modalim just because you feel better. If you stop, your illness may get worse.

Things to be careful of

Taking Modalim with alcohol

One of the side effects of this medicine is muscle problems. Drinking a lot of alcohol may increase the risk 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.

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.

Side Effect

Like all medicines, Modalim can cause side effects, although not everyone 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
- Feeling breathless

- Liver problems. This may cause the eyes or skin to go yellow (jaundice)

Other side effects are:

- Hair loss, balding
- Headache, balance problems
- Feeling dizzy, drowsy or tired
- Impotence

The following side effects can happen at the start of your treatment. You are less likely to get them as treatment continues:

- Feeling sick (nausea) or being sick (vomiting)
- Diarrhea, indigestion or stomach pains

Tell your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days.

Also tell them if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Modalim

Storage

- Keep out of the reach and sight of children.
- 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.
- Store below 30°C

Disposal

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.

Product Description

What it looks like

Modalim tablets are white to off white round tablets with a breakline on one side and embossed 'S170' on the other. They are supplied in cartons of 28 tablets.

Ingredients:

- The active substance is ciprofibrate
- The inactive ingredients are maize starch, lactose monohydrate, microcrystalline cellulose, hypromellose, Hydrogenated vegetable oil, sodium lauryl sulfate

MAL Numbers:

Modalim Tablet 100mg:
MAL19950391A

Manufacturer and Product Registration Holder

Manufacturer

PT Aventis Pharma,
Jl. Jend. A. Yani, Pulo Mas,
Jakarta 13210 – Indonesia.

Product Registration Holder

Sanofi-aventis (Malaysia) Sdn. Bhd.
Unit TB-18-1,
Level 18-1, Tower B, Plaza 33
No.1 Jalan Kemajuan,
Seksyen 13,
46200 Petaling Jaya,
Selangor Darul Ehsan,
Malaysia.

Date of revision

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