

## FIBALIP

*Bezafibrate 200 mg tablets*



### What is in this leaflet

This leaflet answers some common questions about Fibalip.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Fibalip against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

### What Fibalip is used for

Your Fibalip tablets contain the active ingredient bezafibrate. It belongs to a group of medicines known as lipid-lowering substances.

Fibalip is used to help reduce high levels of cholesterol and other fats (lipids) in the blood.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

There is no evidence that Fibalip is addictive.

Fibalip is available on prescription from your doctor.

### Before you take Fibalip

#### *When you must not take it*

**Do not take Fibalip if you have an allergy to:**

- any medicine containing bezafibrate
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take Fibalip if you:**

- have liver disease
- have gallbladder disease
- have severe kidney disease
- have kidney disease and are undergoing dialysis treatment
- have kidney disease and are taking a lipid-lowering agent (an HMG-CoA reductase inhibitor) such as pravastatin, simvastatin or atorvastatin
- are over 70 years of age

**Do not take Fibalip if you are pregnant.** Fibalip may affect your developing baby if you take it during pregnancy.

**Do not take Fibalip if you are breastfeeding.** It is possible that Fibalip passes into breast milk and therefore there is a possibility that your baby may be affected.

**Do not take this medicine if the expiry date printed on the pack has passed or if the packaging is**

**torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

#### *Before you start to take it:*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- nephrotic syndrome, or other kidney problems
- diabetes
- gout
- gallstones
- you have had an organ transplant

Tell your doctor if you are currently taking oestrogen or oestrogen containing contraceptives.

**If you have not told your doctor about any of the above, tell him/her before you start taking Fibalip.**

#### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and Fibalip may interfere with each other. These include:

- oral contraceptives containing oestrogen
- coumarin type anticoagulants (blood

thinning medicines) eg. warfarin

- medicines to treat diabetes including insulin and sulphonylureas
- immunosuppressant medication used for organ transplantation
- perhexiline maleate, a medicine used for chest pain (angina)
- MAO inhibitors, a group of medicines used to treat depression
- anion exchange resins such as colestipol and cholestyramine
- a group of lipid-lowering agents called HMG-CoA reductase inhibitors such as pravastatin, simvastatin or atorvastatin

These medicines may be affected by Fibalip or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## How to take Fibalip

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.**

### ***How much to take***

In adults, the usual daily dose of Fibalip is 200mg (one tablet) three times a day. Tablets should be taken with or after meals and swallowed whole with a glass of water.

Elderly patients and patients with kidney problems may require a lower dose. The dose of Fibalip will be adjusted accordingly by your doctor.

### ***How to take it***

Swallow the tablets whole with a full glass of water.

### ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

Fibalip helps to control your condition, but does not cure it. Therefore Fibalip must be taken everyday. Continue taking Fibalip for as long as your doctor prescribes. Fibalip treatment is usually long term.

### ***If you forget to take it***

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Fibalip. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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## While you are using Fibalip

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### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Fibalip.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**Have your blood fats checked when your doctor says to make sure the medicine is working.**

**If you are about to have any blood tests, make sure your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

### ***Things you must not do***

**Do not take Fibalip to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Fibalip affects you.**

### ***Things that would be helpful for your condition***

Try to make lifestyle changes recommended by your doctor as these may help to improve your condition.

Lifestyle changes your doctor may recommend include:

- following a low fat diet
- losing weight
- increasing physical activity
- reducing the amount of alcohol you may drink
- quit smoking

Your pharmacist may also be able to offer advice.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Fibalip.**

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- loss of appetite, nausea, feelings of fullness in the stomach
- stomach pains, constipation or diarrhoea
- muscle weakness, pain, cramps
- headaches, dizziness
- trouble sleeping

The above list includes the more common side effects of your medicine.

**Tell your doctor as soon as possible if you notice any of the following:**

- numbness, weakness or tingling of the arms and legs
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal

- itchy or raised skin rash, hives or nettlerash
- you feel depressed (have feelings of deep sadness and unworthiness or feel “down”)

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- bleeding or bruising more easily than normal
- severe upper stomach pain with nausea and vomiting
- yellowing of the skin or whites of the eyes (jaundice)
- frequent infections such as fever, severe chills, sore throat and mouth ulcers
- pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## After using Fibalip

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### Storage

**Keep your tablets in the container until it is time to take them.**

If you take the tablets out of the container they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store Fibalip or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### What it looks like

Fibalip tablets are white, round tablets marked with “BZ” over “200” on one side and with a “G” on the other side.

### Ingredients

Each Fibalip tablet contains the active ingredient bezafibrate.

It also contains:

- microcrystalline cellulose
- maize starch
- sodium starch glycollate
- povidone
- purified talc
- magnesium stearate
- colloidal silicon dioxide
- film coat (hypromellose, titanium dioxide, lactose and polyethylene glycol).

This medicine does not contain gluten.

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## If you want to know more

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

## ***Who supplies this medicine***

### **Distributed in New Zealand by:**

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

## ***Date of Information***

7 July 2010

Based on Fibalip datasheet dated  
18 May 2010