

Consumer Medicine Information

BEZALIP[®] and BEZALIP[®] retard

Bezafibrate

200 mg tablets

400 mg sustained release tablets

What is in this leaflet

This leaflet answers some common questions about BEZALIP tablets and BEZALIP retard tablets.

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 BEZALIP or BEZALIP retard against the benefits expected for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What BEZALIP/BEZALIP retard is used for

The names of these medicines are BEZALIP and BEZALIP retard. They contain the active ingredient bezafibrate.

Bezafibrate belongs to a group of medicines known as lipid-lowering substances.

BEZALIP/BEZALIP retard are used to lower high levels of cholesterol and other fats (lipids) in the blood. These high levels themselves do not make people feel ill but may cause problems later on, leading to heart disease or other illness.

Your doctor, however, may have prescribed BEZALIP/BEZALIP retard for another purpose.

Ask your doctor if you have any questions why BEZALIP/BEZALIP retard has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take BEZALIP/BEZALIP retard

When you must not take it

Do not take BEZALIP/BEZALIP retard if:

1. you have had an allergic reaction to BEZALIP/BEZALIP retard or any other type of "fibrate" including a reaction to light, or any ingredients listed at the end of this leaflet
2. you have gall bladder disease
3. you have liver disease

4. **you have severe kidney disease**
5. **you have kidney disease and are undergoing dialysis treatment**
6. **you have kidney disease and are taking a lipid-lowering agent (an HMG-CoA reductase inhibitor) such as pravastatin (Pravachol[®]), simvastatin (Lipex[®]) or atorvastatin (Lipitor[®])**
7. **you are pregnant or breastfeeding**
8. **you are over 70 years of age**
9. **the pack is damaged or shows signs of tampering**
10. **the expiry date printed on the pack has passed.**
If the pharmacist has repacked the medicine for you, there may not be an expiry date on the pack. If you use this medicine after the expiry date has passed it may not work as well, or may have an unexpected effect.

If you are not sure if you should be taking BEZALIP/BEZALIP retard, talk to your doctor.

Before you start to take it:

Tell your doctor if:

1. **you are pregnant or intend to become pregnant**
you should not take BEZALIP/BEZALIP retard if you are pregnant
2. **you are breastfeeding or wish to breastfeed**
you should not take BEZALIP/BEZALIP retard if you are breastfeeding
3. **you have any other health problems including:**
 - diabetes
 - gout
 - gallstones
 - you have had an organ transplant, including a bone marrow transplant
4. **you are allergic to any other medicines, foods, dyes or preservatives**

If you have not told your doctor about any of the above, do so before you start taking BEZALIP/BEZALIP retard.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health-food shop.

Some commonly used medicines that may interfere with BEZALIP/BEZALIP retard. These medicines include:

- oral contraceptives containing oestrogen
- medicines for diabetes including insulin and a group of medicines called sulphonylureas which include gliclazide (Diamicron[®]), tolbutamide (Diatol[®]), glibenclamide (Gliben[®]) and glipizide (Minidiab[®])
- medicines for thinning the blood e.g. warfarin (Marevan[®], Coumadin[®])
- perhexiline maleate (Pexsig[®]), a medicine for angina (chest pain)
- antidepressant medicines called monoamine oxidase inhibitors (MAOI's). Common MAOI's are phenelzine (Nardil[®]) and tranylcypromine (Parnate[®])
- a group of lipid-lowering agents called HMG-CoA reductase inhibitors. Common HMG-CoA reductase inhibitors are pravastatin (Pravachol[®]), simvastatin (Lipex[®]) and atorvastatin (Lipitor[®]).

- anion exchange resins such as colestipol (Colestid[®]) and cholestyramine (Questran Light[®]) can prevent BEZALIP/BEZALIP retard from working if they are taken at the same time. These medicines should be taken at least 2 hours before or after BEZALIP/BEZALIP retard is taken
- immunosuppressant agents for organ transplantation

These medicines may be affected by BEZALIP/BEZALIP retard or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking BEZALIP/BEZALIP retard.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take BEZALIP/BEZALIP retard

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

They may differ from the information contained in this leaflet.

How much to take

Take BEZALIP/BEZALIP retard exactly as your doctor has prescribed.

Your doctor will tell you how many BEZALIP/BEZALIP retard tablets to take each day.

The usual dose of BEZALIP 200 mg tablets is one tablet three times each day. Your doctor may tell you to take fewer tablets each day, especially if you have a good response to BEZALIP.

The usual dose of BEZALIP retard 400 mg tablets is one tablet once a day.

If you have renal disease, your doctor will probably tell you to take fewer BEZALIP 200 mg tablets than the usual dose.

How to take it

Swallow the tablets whole with a drink of water. Take the tablets with, or after, meals.

How long to take it

High cholesterol and other blood fats need long term treatment.

Continue taking BEZALIP/BEZALIP retard until your doctor tells you to stop.

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.

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

If you have trouble remembering your dose, ask your pharmacist for some hints.

In case of an overdose

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766, or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much BEZALIP/BEZALIP retard. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking BEZALIP/BEZALIP retard

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking BEZALIP/BEZALIP retard.

Do not take any other medicines whether they require a prescription or not, without first telling your doctor or pharmacist.

Tell your doctor if you become pregnant while taking BEZALIP/BEZALIP retard.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your medicine unnecessarily.

Try to make lifestyle changes your doctor may have recommended, such as watching your diet, losing weight or increasing physical activity and how much alcohol you may drink, as these will help to improve your condition. Your pharmacist may also be able to offer advice.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Things you must not do

Do not stop taking BEZALIP/BEZALIP retard or lower the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give BEZALIP/BEZALIP retard to anyone else, even if they have the same condition as you.

Do not use BEZALIP/BEZALIP retard to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how BEZALIP/BEZALIP retard affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BEZALIP/BEZALIP retard.

BEZALIP/BEZALIP retard 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 treatment if you get some of the side effects. Your doctor may wish to test your blood from time to time.

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

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

- at first your stomach may feel full or you might feel sick (nausea), but this discomfort should go away in a few days.
- You may have stomach pains, constipation or diarrhoea
- loss of appetite or indigestion
- pins and needles or other sensations
- you may get a headache or feel dizzy. If these effects are troublesome talk to your doctor.
- if you develop a rash or pains or weakness, especially in your arms or legs, or your skin becomes sensitive to light, tell your doctor.
- you might start to feel tired or in some cases notice you begin to bruise easily. If so, tell your doctor.
- high levels of blood fats (cholesterol) may cause gallstones. If you have troublesome pain in the upper part of the stomach or yellowing of the skin (jaundice) while you are taking BEZALIP/BEZALIP retard tell your doctor.
- a small number of patients have had increased hair loss.
- in men, rare cases of impotence have been reported, although other causes are possible.
- Depression, difficulty sleeping or memory loss.

In general, most of these side effects clear up once the tablets are stopped.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking BEZALIP/BEZALIP retard

Storage

Keep your tablets in the blister pack and carton until it is time to take them.

If you take the tablets out of the blister or the carton they may not keep well.

Keep BEZALIP/BEZALIP retard in a cool, dry place where the temperature stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep BEZALIP/BEZALIP retard in a safe place 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 BEZALIP/BEZALIP retard, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

Availability

BEZALIP tablets come in one strength, 200 mg.
BEZALIP comes in one pack size of 90 tablets.

BEZALIP retard tablets come in one strength, 400 mg.
BEZALIP retard comes in one pack size of 30 sustained release tablets.

What BEZALIP/BEZALIP retard look like

BEZALIP 200 mg tablets are white, round film coated tablets imprinted 'G6' on the reverse.

BEZALIP retard 400 mg tablets are white, round film-coated tablets engraved D9 on one face.

Ingredients

Active ingredient

The active ingredient in BEZALIP and in BEZALIP retard is bezafibrate.

Each 200 mg Bezalip tablet contains 200 mg of bezafibrate.

Each 400 mg Bezalip retard tablet contains 400 mg of bezafibrate.

Inactive ingredients

Bezalip 200 mg tablets also contain maize starch, pregelatinised starch, microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycollate, magnesium stearate and Opadry White II.

Bezalip retard 400 mg tablets also contain lactose, polyvidone "K 25", sodium lauryl sulphate, hypromellose, colloidal silicon dioxide, magnesium stearate, poly(ethylacrylate, methylmethacrylate), polyethylene glycol, talc, titanium dioxide, polysorbate 80, and sodium citrate.

Supplier

Teva Pharma (New Zealand) Limited
Auckland, New Zealand

This leaflet was prepared on 21 February 2017.

Reference: New Zealand Data Sheet dated 21 February 2017.