PART III: CONSUMER INFORMATION

PR BEZALIP® SR
Bezafibrate sustained release tablets

This leaflet is part III of a three-part "Product Monograph" published when BEZALIP SR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BEZALIP SR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
BEZALIP SR is used:

- to treat patients with hyperlipidemia (high cholesterol)
- to treat patients with high to very high levels of triglycerides (a type of fat in the body that is an important energy source forming much of the fat stored in the body).

This medicine should only be used to supplement an appropriate diet recommended and followed up by your doctor for the long-term treatment of raised lipid levels: prescription of this medicine in no way replaces dietary treatment. In addition, depending on the situation, your doctor may recommend further physical exercise, weight loss or other measures.

What it does:
BEZALIP SR lowers cholesterol and high triglyceride levels in the blood. When taken by patients who previously suffered a heart attack, BEZALIP SR has been shown to slow down any hardening of the arteries, and can help prevent a second heart attack. BEZALIP SR is only available on prescription.

When it should not be used:
BEZALIP SR should not be used:

- if you have severe liver damage
- if you have kidney disease, kidney damage, or if you are on dialysis
- if you have a pre –existing gallbladder disease
- if you are allergic to bezafibrate, any component of BEZALIP SR or to other cholesterol lowering medications known as Fibrates. For a complete list of the components of BEZALIP SR, please see "**What the nonmedicinal ingredients are**".
- if you have taken BEZALIP SR or any other drug in the fibrate class before and it has caused a sensitivity reaction, including sensitivity to sun.
- if you are pregnant or breast feeding
- if you have very high levels of lipids, a condition known as Type 1 hyperlipoproteinemia
- If you are taking other cholesterol lowering medication known as Statins and are predisposed to develop muscle weakness

What the medicinal ingredient is:
The medicinal ingredient in BEZALIP SR is bezafibrate.

What the nonmedicinal ingredients are:
Colloidal silicon dioxide, hydroxypropyl methylcellulose 2208 & 2910, lactose, magnesium stearate, methyl methacrylate, polyethyl acrylate, polyethylene glycol, 10000, polysorbate 80, povidone K25, sodium citrate, sodium lauryl sulphate, talc, and titanium dioxide.

What dosage forms it comes in:
BEZALIP SR is a sustained release 400 mg tablet.

WARNINGS AND PRECAUTIONS

BEFORE you use BEZALIP SR talk to your doctor or pharmacist if:

- if you have taken BEZALIP SR or any other drug in the fibrate class before and if it caused an allergy or was otherwise poorly tolerated.
- if you suffer from liver or kidney problems. BEZALIP SR should not be used in elderly patients above the age of 70.
- if you are pregnant or intend to become pregnant. BEZALIP SR should not be taken during pregnancy. If you are a woman who could become pregnant, use adequate contraception during treatment. In the event of pregnancy during treatment, BEZALIP SR should be discontinued and the physician should be informed.
- If you are breast feeding, or intend to breast feed. BEZALIP SR should not be taken while breast-feeding.
- if you are taking other medicines prescribed by your doctor, in particular an oral anticoagulant such as warfarin (WARFILONE) or cyclosporine (SANDIMMUNE, NEORAL).
- If you are taking any over-the-counter medicines or herbal supplements.

Inform your doctor of any health problem that occurs while taking BEZALIP SR as well as any prescription or non-prescription medicine. If you need other medical treatment let the doctor know that you are taking BEZALIP SR. Safety in children and young adolescents has not been established with BEZALIP SR.

This medicine is prescribed for a particular health problem and for your personal use. Do not give it to other persons.

BEZALIP SR tablets should not be used after the expiry on the pack.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with BEZALIP SR include:

- Anticoagulants (blood thinners)
- Immunosupressants (medication that lowers the body's ability to defend itself against foreign substances)
- HMG CoA reductase inhibitors or stains (cholesterol lowering medication)
- Cyclosporine
- MAO-inhibitors (antidepressants)
- Estrogens
- Bile acid resins (cholesterol lowering medications)

If you are taking both BEZALIP SR and a bile acid resin concurrently, an interval of 2 hours should be maintained between the two drugs.

PROPER USE OF THIS MEDICATION

Usual dose:
Standard dosage is one 400 mg sustained release tablet once (1) daily, taken in the morning or evening with or after meals. The sustained release tablet should be swallowed whole with sufficient fluid. Do not chew BEZALIP SR tablets.

Comply exactly to the terms of the prescription. Do not change the dose without your doctor's advice. Consult your doctor before stopping treatment since to do so may result in an increase in your blood lipid levels.

Your doctor will ask you to have regular medical check-ups and laboratory tests. It is important to respect the dates proposed: we strongly recommend that you keep faithfully these appointments.

BEZALIP SR is only available on prescription. This medicine should only be used to supplement an appropriate diet recommended and followed up by your doctor for the long-term treatment of raised lipid levels: prescription of this medicine in no way replaces dietary treatment. In addition, depending on the situation, your doctor may recommend further physical exercise, weight loss or other measures.

Overdose:
In cases of overdose or suspected overdose, contact the poison control centre or your physician immediately**.**

Missed Dose:
Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular regular dosing schedule. Do not take 2 doses at the same time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, BEZALIP SR can have side effects. The most common side effects are rash, headache, diarrhoea, nausea and abdominal pain.

Tell your doctor if you are unwell while taking BEZALIP SR.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
More Common	Diarrhoea Constipation Abdominal Pain Skin reactions	√		
Less common	Muscular pain, weakness or cramps Dizziness Fast decrease in kidney function (ie decreased amount of urine output to almost none)		√	

This is not a complete list of side effects. For any unexpected effects while taking BEZALIP SR, contact your doctor or pharmacist.

HOW TO STORE IT

Store BEZALIP SR between 15-30°C.
Store in a dry place.
Keep all medicines out of reach of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.aralez.comor by contacting the marketing agent for Canada, Aralez Pharmaceuticals Canada Inc.,
MEDICAL INFORMATION SAFETY LINE (toll-free)
1-866-391-4503

This leaflet was prepared by Allergan Inc., Markham, ON, L6G 0B5

Warfilone® is a registered Trade-Mark of Merck Frosst Canada & co
Sandimmune® is a registered Trade-Mark of Novartis AG
Neoral® is a registered Trade-Mark of Novartis AG
Bezalip® is a registered Trade-Mark of Allergan Pharmaceuticals International Limited, used under licence by Allergan Inc.

Allergan® and its design are trademarks of Allergan Inc.
Imported and Marketed By: Aralez Pharmaceuticals Canada Inc., Mississauga, ON, L5N 0E4
www.aralez.com
Last revised: October 31, 2019