

PART III: CONSUMER INFORMATION



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

Since you are taking VICTRELIS™ with peginterferon alpha/ribavirin, also read the leaflet related to these medications.

ABOUT THIS MEDICATION**What the medication is used for:**

VICTRELIS™ is a prescription medicine used with peginterferon alpha plus ribavirin to treat chronic (lasting a long time) hepatitis C genotype 1 infection in adults who have not been previously treated or who have failed previous therapy. Patients with hepatitis C have the virus in their blood and in their liver.

It is not known if VICTRELIS™ is safe and effective when used in children (< 18 years of age).

What it does:

VICTRELIS™ is a medicine called a Hepatitis C Virus Protease Inhibitor that directly targets Hepatitis C Virus to reduce the amount of virus in your body.

When it should not be used:

Do not use VICTRELIS™ in combination with peginterferon alpha/ribavirin:

- if you are hypersensitive (allergic) to boceprevir or to any of the excipients (see *What the non-medicinal ingredients are*);
- if you have certain types of hepatitis (autoimmune hepatitis);
- if you have advanced, uncontrolled liver disease (other than hepatitis C);
- if you are taking certain medicines. For more information about medicines that you should not take while using VICTRELIS™, please see *Interactions with this Medication*;
- if you or your partner are pregnant.

What the medicinal ingredient is:

boceprevir

What the non-medicinal ingredients are:

croscarmellose sodium, gelatin, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pre-gelatinized starch, red iron oxide, shellac, sodium lauryl sulfate, titanium dioxide, yellow iron oxide

What dosage forms it comes in:

Each hard capsule contains 200 mg of boceprevir.

WARNINGS AND PRECAUTIONS

BEFORE you use VICTRELIS™, talk to your doctor or pharmacist if:

- you have ever had certain blood disorders such as anemia or neutropenia;
- you have liver problems other than hepatitis C infection;
- you are breastfeeding. It is not known if VICTRELIS™ passes into breast milk and whether it could harm your baby;
- you have Human Immunodeficiency Virus (HIV), any immunity problems, or have had an organ transplant;
- you have any other medical condition; or
- you are using any other medications.

VICTRELIS™ may cause a Reduction of Red Blood Cells a condition known as anemia, or a reduction of neutrophils (a type of white blood cell) a condition known as neutropenia. Anemia or neutropenia may be increased when VICTRELIS™ is added to your ribavirin therapy. Therefore, your healthcare provider will be checking your blood counts periodically for possible decreases in your blood cell counts. Depending on the medications that you are taking, your healthcare provider may make changes to your current medicines or prescribe additional medicines to treat your anemia, or neutropenia.

VICTRELIS™ may cause serious side effects when taken with other medications. It is important to know the medicines that should not be taken with VICTRELIS™.

Do not take the combination of VICTRELIS™ with peginterferon alpha/ribavirin if you or your partner are pregnant. Ribavirin may cause birth defects or death of your unborn baby. Ribavirin should not be taken by women who are pregnant and pregnancy should be avoided during use and up to 6 months after the last dose of ribavirin. As systemic (e.g., oral, topical...) hormonal contraceptives may not work as well while taking VICTRELIS™, use of 2 alternative methods of contraception, such as barrier method and intrauterine devices during treatment with VICTRELIS™ and ribavirin. If your healthcare provider has prescribed ribavirin as part of your treatment, read the ribavirin leaflet and discuss with your doctor.

IMPORTANT: PLEASE READ

Do not take VICTRELIS™ alone to treat Chronic Hepatitis C infection. VICTRELIS™ should only be used with other medicines, ribavirin and peginterferon alpha, to treat Chronic Hepatitis C infection.

INTERACTIONS WITH THIS MEDICATION

Do not take VICTRELIS™ if you take:

- alfuzosin - used to treat enlarged prostate;
- amiodarone, propafenone and quinidine - used for heart beat problems;
- astemizole¹, terfenadine¹ - used to treat allergies, hives, itching and watery eyes;
- birth control pills that contain drospirenone;
- carbamazepine, phenobarbital, phenytoin - used to treat seizures and nerve pain;
- cisapride¹ – used to help with digestion;
- ergot-containing medicines used to treat migraines, such as:
 - ergotamine,
 - dihydroergotamine,
 - ergonovine,
 - methylergonovine;
- lovastatin, simvastatin - used for lowering high cholesterol and triglycerides;
- oral midazolam, oral triazolam - used to help you sleep;
- pimozide – used for mental health problems;
- rifampin – used to treat tuberculosis or meningitis;
- sildenafil and tadalafil - used for the treatment of pulmonary arterial hypertension;
- St. John's Wort - an herbal product used to help with your mood.

Tell your doctor if you are taking any of the following medications as they may interact with VICTRELIS™. The dosage of one or the other may have to be changed or the medication avoided:

¹ Please note that cisapride, astemizole and terfenadine are no longer available on the Canadian market.

- atorvastatin, bepridil, bosentan, budesonide, buprenorphine, colchicine, cyclosporine, desipramine, dexamethasone, digoxin, felodipine, fluticasone, fluvastatin, methadone, nifedipine, nifedipine, pravastatin, rifabutin, rosuvastatin, salmeterol, sirolimus, tacrolimus, trazodone, and warfarin

PROPER USE OF THIS MEDICATION

- Take VICTRELIS™ **exactly** as your healthcare provider tells you. Your healthcare provider will tell you how much to take and when to take it.
- **Always take VICTRELIS™ with food (a meal or a snack, such as a piece of fruit or crackers).**
- Each dose (four 200 mg capsules) of VICTRELIS™ should be taken 7 to 9 hours apart.

Usual Adult Dose:

VICTRELIS™ 800 mg Three Times Daily will be used in combination with peginterferon alpha/ribavirin. VICTRELIS™ will only be added to the treatment from the start of the fifth week, i.e. the day of your week 4 visit. The total duration of your treatment will depend on the way in which your virus responds to treatment.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of VICTRELIS™ and it is less than 2 hours before the next dose is due, the missed dose should be skipped. If you miss a dose and it is more than 2 hours before the next dose is due, take the missed dose with food and continue the normal dosing schedule. Do not double the next dose. If you have questions about what to do, call your healthcare provider.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

VICTRELIS™ may cause serious side effects, including:

- **Blood problems.** VICTRELIS™ can cause low red cell counts (anemia) or low neutrophil (neutropenia), which is a type of white blood cell, and low platelet counts (thrombocytopenia). In some people, these blood counts may fall to dangerously low levels.

Tell your provider right away if you have any side effect that bothers you or that does not go away.

The most common side effects of VICTRELIS™ in combination with ribavirin and peginterferon alpha include:

IMPORTANT: PLEASE READ

- fatigue, low red blood cell count (anemia), change in sense of taste, nausea, headache, diarrhea, vomiting, abdominal pain, fever, muscle and joint pain, weight loss, difficulty in sleeping, and dry skin
- fatigue, dizziness, fainting changes in blood pressure, and blurred vision can occur, so be cautious before driving or operating heavy machinery.

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	
Very common	Blood problems: low red cell counts (anemia) which may lead to tiredness, headaches, shortness of breath when exercising, dizziness and looking pale.		√	
	Blood problems: low white blood cell counts (neutropenia) which may lead to an increased risk of getting infections.		√	

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

Since you are taking VICTRELIS™ with peginterferon alpha/ribavirin, also read the leaflet related to these medications.

HOW TO STORE IT

VICTRELIS™ Capsules should be refrigerated at 2°C – 8°C until dispensed by a pharmacist. For patient use, refrigerated capsules of VICTRELIS™ can remain stable until the expiration date printed on the label. VICTRELIS™ can also be stored at room temperature (15°C – 30°C) for up to 3 months. Store in the original container.

Keep VICTRELIS™ and all medicines out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-496-9092, or
 - Mail to: Merck Canada Inc.
Pharmacovigilance
P.O. Box 1005
Pointe-Claire - Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program or Merck does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Merck Canada Inc. at: 1-800-567-2594.

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