

MEDICATION GUIDE
VICTRELIS® (vic-TREL-is)
(boceprevir)
capsules

Read this Medication Guide before you start taking VICTRELIS and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

VICTRELIS is taken along with peginterferon alfa and ribavirin. You should also read those Medication Guides.

What is the most important information I should know about VICTRELIS?

VICTRELIS, in combination with peginterferon alfa and ribavirin, may cause birth defects or death of your unborn baby. If you are pregnant or your sexual partner is pregnant or plans to become pregnant, do not take these medicines. You or your sexual partner should not become pregnant while taking VICTRELIS, peginterferon alfa, and ribavirin combination therapy and for 6 months after treatment is over.

- **Females and males must use 2 effective forms of birth control during treatment and for 6 months after treatment with VICTRELIS, peginterferon alfa, and ribavirin combination therapy.** Hormonal forms of birth control such as implants, injections, vaginal rings, and some birth control pills may not work during treatment with VICTRELIS. The use of certain types of birth control pills may be acceptable. Talk to your healthcare provider about forms of birth control that may be used during this time.
- Females must have a pregnancy test before starting treatment with VICTRELIS, peginterferon alfa, and ribavirin combination therapy, every month while being treated, and every month for 6 months after treatment with VICTRELIS, peginterferon alfa, and ribavirin combination therapy is over.
- If you or your female sexual partner becomes pregnant while taking VICTRELIS, peginterferon alfa, and ribavirin combination therapy or within 6 months after you stop taking these medicines, tell your healthcare provider right away. You or your healthcare provider should contact the Ribavirin Pregnancy Registry by calling 1-800-593-2214. The Ribavirin Pregnancy Registry collects information about what happens to mothers and their babies if the mother takes ribavirin while she is pregnant.
- **Do not take VICTRELIS alone to treat chronic hepatitis C infection.** VICTRELIS must be used with peginterferon alfa and ribavirin to treat chronic hepatitis C infection.

What is VICTRELIS?

VICTRELIS is a prescription medicine used with the medicines peginterferon alfa and ribavirin to treat long-lasting (chronic) hepatitis C genotype 1 infection in adults with stable (compensated) liver disease who have not been treated before or who have failed previous treatment.

It is not known if VICTRELIS is safe and effective in children under 18 years of age.

Who should not take VICTRELIS?

See “What is the most important information I should know about VICTRELIS?”

Do not take VICTRELIS if you:

- have had an allergic reaction to boceprevir or any of the ingredients in VICTRELIS. See the end of this Medication Guide for a complete list of ingredients in VICTRELIS.
- take certain medicines. **VICTRELIS may cause serious side effects when taken with certain medicines.** Read the section "**What should I tell my healthcare provider before taking VICTRELIS?**"

Talk to your healthcare provider before taking VICTRELIS if you have any of the conditions listed below.

What should I tell my healthcare provider before taking VICTRELIS?

Before and while you take VICTRELIS, tell your healthcare provider if you:

- have certain blood disorders such as low red blood cell count (anemia), a certain type of low white blood cell count (neutropenia) or combination of low platelet, red and white blood cell counts (pancytopenia)
- have liver failure
- have liver problems other than hepatitis C infection
- have had a liver or other organ transplant
- plan to have surgery
- have any other medical condition
- are breastfeeding. It is not known if VICTRELIS passes into breast milk. You and your healthcare provider should decide if you will take VICTRELIS or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

VICTRELIS and other medicines may affect each other. This can cause you to have too much or not enough VICTRELIS or your other medicines in your body, affecting the way VICTRELIS and your other medicines work, or causing side effects that can be serious or life-threatening. Do not start taking a new medicine without telling your healthcare provider or pharmacist.

Do not take VICTRELIS if you take a medicine that contains:

- alfuzosin hydrochloride (UROXATRAL[®])
- anti-seizure medicines:
 - carbamazepine (CARBATROL[®], EPITOL[®], EQUETRO[®], TEGRETOL[®], TEGRETOL[®] XR, TERIL[™])
 - phenobarbital
 - phenytoin (DILANTIN[®])
- cisapride (PROPULSID[®])
- drospirenone-containing birth control medicines, including:
 - YAZ[®], YASMIN[®], ZARAH[®], OCELLA[®], GIANVI[®], BEYAZ[®], ANGELIQ[®], LORYNA[®], SYEDA[®], SAFYRAL[®]
- doxazosin (CARDURA[®], CARDURA[®] XL)
- ergot-containing medicines, including:
 - dihydroergotamine mesylate (D.H.E. 45[®], MIGRANAL[®])
 - ergonovine and methylergonovine (ERGOTRATE[®], METHERGINE[®])

- ergotamine tartrate (CAFERGOT[®], MIGERGOT[®], ERGOMAR[®], ERGOSTAT, MEDIHALER ERGOTAMINE, WIGRAINE, WIGRETTES)
- lovastatin (ADVICOR[®], ALTOPREV[®], MEVACOR[®])
- lurasidone (LATUDA[®])
- midazolam, when taken by mouth
- pimozone (ORAP[®])
- rifampin (RIFADIN[®], RIFAMATE[®], RIFATER[®], RIMACTANE)
- sildenafil (REVATIO[®]), when used for treating lung problems
- silodosin (RAPAFLO[®])
- simvastatin (SIMCOR[®], VYTORIN[®], JUVISYNC[®], ZOCOR[®])
- St. John's Wort (*Hypericum perforatum*) or products containing St. John's Wort
- tadalafil (ADCIRCA[®]), when used for treating lung problems
- tamsulosin (FLOMAX[®], JALYN[®])
- triazolam (HALCION[®])

Tell your healthcare provider if you are taking or starting to take any of these medicines:

- atazanavir (REYATAZ[®])
- clarithromycin (BIAXIN[®], BIAXIN[®] XL, PREVPAC[®])
- darunavir (PREZISTA[®])
- dexamethasone
- efavirenz (SUSTIVA[®], ATRIPLA[®])
- etravirine (INTELENCE[®])
- itraconazole (ONMEL[®], SPORANOX[®])
- ketoconazole (NIZORAL[®])
- lopinavir (KALETRA[®])
- posaconazole (NOXAFIL[®])
- rifabutin (MYCOBUTIN[®])
- ritonavir (NORVIR[®], KALETRA[®])
- voriconazole (VFEND[®])

Your healthcare provider may need to monitor your therapy more closely if you take VICTRELIS with the following medicines. Talk to your healthcare provider if you are taking or starting to take a medicine that contains:

- alprazolam (XANAX[®])
- amiodarone (CORDARONE[®], NEXTERONE[®], PACERONE[®])
- amlodipine (AMTURNIDE[®], NORVASC[®], TEKAMLO[®])
- atorvastatin (LIPITOR[®])
- bepridil (VASCOR)
- bosentan (TRACLEER[®])
- budesonide (PULMICORT[®], PULMICORT FLEXHALER[®], RHINOCORT[®], PULMICORT RESPULES[®], SYMBICORT[®])
- buprenorphine (BUTRANS[®], BUPRENEX[®], SUBOXONE[®], SUBUTEX[®])
- cyclosporine (GENGRAF[®], NEORAL[®], SANDIMMUNE[®])
- desipramine (NORPRAMIN[®])

- digoxin (LANOXIN[®])
- diltiazem (CARDIZEM[®], CARDIZEM[®] CD, CARDIZEM[®] LA, CARTIA XT[®], DILACOR XR[®], DILT-CD, DILTZAC, TIAZAC[®], TAZTIA XT[®])
- escitalopram (LEXAPRO[®])
- felodipine (PLENDIL[®])
- fluticasone (VERAMYST[®], FLOVENT[®] HFA, FLOVENT[®] DISKUS, ADVAIR[®] HFA, ADVAIR DISKUS[®])
- hormonal forms of birth control, including birth control pills, vaginal rings, implants and injections
- hormone replacement therapy
- methadone (METHADOSE[®], DOLOPHINE[®])
- naloxone
- nifedipine (PROCARDIA[®], ADALAT[®] CC, PROCARDIA XL[®], AFEDITAB[®] CR)
- nicardipine (CARDENE[®] SR, CARDENE[®])
- nisoldipine (SULAR[®])
- omeprazole
- prednisone
- oral and IV prednisolone
- pravastatin (PRAVACHOL[®])
- propafenone (RYTHMOL[®], RYTHMOL[®] SR)
- quinidine
- raltegravir (ISENTRESS[®])
- salmeterol (ADVAIR[®] HFA, ADVAIR DISKUS[®], SEREVENT[®])
- sildenafil (VIAGRA[®]), when used for treating erectile dysfunction
- sirolimus (RAPAMUNE[®])
- tacrolimus (PROGRAF[®])
- tadalafil (CIALIS[®]), when used for treating erectile dysfunction
- colchicine (COLCRYS[®], Probenecid and Colchicine, COL-Probenecid)
- trazodone (OLEPTRO[®])
- vardenafil (STAXYN[®], LEVITRA[®]), when used for treating erectile dysfunction
- verapamil (CALAN[®], CALAN[®] SR, COVERA-HS[®], TARKA[®], VERELAN[®], VERELAN[®] PM)
- warfarin (COUMADIN[®], JANTOVEN[®])

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take VICTRELIS?

- Take VICTRELIS exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much to take and when to take it.
- Take VICTRELIS with food (a meal or light snack).
- VICTRELIS is packaged into single daily-use bottles. Each bottle has your entire day's worth of medicine. Make sure you are taking the correct amount of medicine each time.
- If you miss a dose of VICTRELIS and it is less than 2 hours before the next dose, the missed dose should be skipped.

- If you miss a dose of VICTRELIS and it is 2 or more hours before the next dose, take the missed dose with food. Take your next dose at your normal time and continue the normal dosing schedule.
- Do not double the next dose. If you have questions about what to do, call your healthcare provider.
- Your healthcare provider should do blood tests before you start treatment, at weeks 2, 4, 8, 12 and 24, and at other times as needed during treatment, to see how well the medicines are working and to check for side effects.
- If you take too much VICTRELIS, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of VICTRELIS?

VICTRELIS may cause serious side effects, including:

See “What is the most important information I should know about VICTRELIS?”

Serious allergic reactions. Serious allergic reactions can happen and may become severe requiring treatment in a hospital. Tell your healthcare provider right away if you have any of these symptoms:

- itching
- hives
- swelling of your face, eyes, lips, tongue, or throat
- trouble breathing or swallowing

Blood problems. VICTRELIS can affect your bone marrow and cause low red blood cell, low white blood cell, and low platelet counts. In some people, these blood counts may fall to dangerously low levels. If your blood cell counts become very low, you can get anemia, infections, or bleed easily.

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

- tiredness
- nausea
- headache
- change in taste

Additionally, while the medicine has been on the market, serious skin reactions, including blistering or peeling of the skin, and infections of the blood and pneumonia have been reported. Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of VICTRELIS. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VICTRELIS?

- Store VICTRELIS capsules in a refrigerator at 36 to 46°F (2 to 8°C). Safely throw away refrigerated VICTRELIS after the expiration date.
- VICTRELIS capsules may also be stored at room temperature up to 77°F (25°C) for 3 months.
- Keep VICTRELIS in a tightly closed container and away from heat.

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

General information about the safe and effective use of VICTRELIS.

It is not known if treatment with VICTRELIS will prevent you from infecting another person with the hepatitis C virus during your treatment. Talk with your healthcare provider about ways to prevent spreading the hepatitis C virus.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VICTRELIS for a condition for which it was not prescribed. Do not give VICTRELIS to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about VICTRELIS. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about VICTRELIS that is written for health professionals.

For more information, go to www.victrelis.com or call 1-877-888-4231.

What are the ingredients in VICTRELIS?

Active ingredients: boceprevir

Inactive ingredients: sodium lauryl sulfate, microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, pre-gelatinized starch, and magnesium stearate.

Red capsule shell: gelatin, titanium dioxide, D&C Yellow #10, FD&C Blue #1, FD&C Red #40.

Yellow capsule shell: gelatin, titanium dioxide, D&C Yellow #10, FD&C Red #40, FD&C Yellow #6.

Red printing ink: shellac, red iron oxide. **Yellow printing ink:** shellac, titanium dioxide, povidone, D&C Yellow #10 Aluminum Lake.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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For patent information: www.merck.com/product/patent/home.html

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