



BOCEPREVIR (Victrelis)

WHAT IS BOCEPREVIR?

Boceprevir is a drug used as part of antiviral therapy against hepatitis C virus (HCV). The trade name is Victrelis. It is manufactured by Merck. Boceprevir is an HCV protease inhibitor. These drugs prevent the protease enzyme from working. This makes it harder for the virus to multiply. See Step 6 of the HCV life cycle shown in Fact Sheet 670.

Boceprevir is one of the first drugs that directly interfere with the HCV life cycle. Earlier drugs used to treat HCV were interferon and ribavirin (IFN/RBV, see fact sheet 680.) They are primarily general immune boosters. Boceprevir must be used in combination with pegylated interferon and ribavirin (pegIFN/RBV). It should not be used by itself.

WHO SHOULD TAKE IT?

Boceprevir was approved in 2011 as an antiviral drug for people infected with HCV genotype 1 whose liver is still functioning. People with decompensated (unstable) liver cirrhosis, should not take boceprevir. Signs of decompensated cirrhosis may include bleeding due to varices, (swelling i veins) in the throat and stomach, ascites (accumulation of fluid in the abdomen) or encephalopathy (brain damage that causes personality changes or problems thinking).

Boceprevir has not been studied in people less than 18 years old, or in liver transplant patients. There is limited information on people who are also infected with HIV or with hepatitis B. Taking boceprevir along with pegIFN/RBV gives you a much better chance of clearing HCV genotype 1 infection than just taking pegIFN/RBV.

WHAT ABOUT DRUG RESISTANCE?

Some new copies of HCV carry mutations, meaning they are slightly different from the original virus. Some mutated virus can keep multiplying even when you are taking anti-HCV medications. When this happens, the drug will stop working. This is called "developing resistance" to the drug.

Resistance can develop quickly. It is very important to take antiviral medications according to instructions, on schedule, and not to skip or reduce doses.

If your HCV viral load is too high after 4 weeks of treatment, your doctor might

decide that you should stop taking boceprevir to avoid having your HCV develop resistance.

HOW IS IT TAKEN?

Treatment is started with 4 weeks of peg IFN/RBV, known as a "lead in" period. Boceprevir is added during week 5. It is taken by mouth as 200 milligram (mg) tablets. The normal adult dose is 800 mg 3 times a day. Take the doses 7 to 9 hours apart. You will take 4 tablets each time or 12 tablets daily. Boceprevir must be taken with pegIFN/RBV. Interferon is injected under the skin, and ribavirin is taken by mouth. Fact sheet 680 has more information on these medications.

Boceprevir use is based on "response guided therapy." The length of treatment depends on how well boceprevir controls HCV viral load early in treatment. **Good response** is when HCV viral load becomes undetectable within the first 8 weeks of treatment and stays undetectable. **Moderate response** is when HCV viral load stays detectable during the first 8 weeks of treatment, but becomes undetectable by 24 weeks of treatment. **Treatment failure** is when viral load is over 100 units per milliliter at week 12 or is detectable at week 24. If this occurs, boceprevir should be stopped.

Patients without cirrhosis who have not yet started HCV treatment:

- Good response: treatment for 7 months.
- Moderate response: treatment with boceprevir continues for 36 weeks (9 months) followed by 12 more weeks (3 months) of pegIFN/RBV therapy.

Patients without cirrhosis who were previously treated for HCV:

- Good response: treatment ends after 9 months.
- Moderate response: treatment with boceprevir continues for 36 weeks followed by 12 more weeks (3 months) of pegIFN/RBV therapy.

Patients with stable cirrhosis should take pegIFN/RBV for 4 weeks, and then add boceprevir for 44 more weeks. Boceprevir must be taken with a meal or light snack to increase blood levels of the drug. Boceprevir can be stored in the refrigerator. It is also stable at room temperature for up to 3 months.

WHAT ARE THE SIDE EFFECTS?

Boceprevir can cause a reduction of red blood cell counts (anemia, see fact sheet 552.) Boceprevir can also cause neutropenia, a shortage of a type of white blood cell. Neutropenia can be caused by interferon; boceprevir can make it worse. Other common side effects of boceprevir include nausea, diarrhea, and a metallic taste (called dysgeusia) that goes away after boceprevir is stopped.

Because boceprevir is always taken in combination with ribavirin, which can cause serious birth defects, do not take telaprevir if you or your sexual partner are pregnant or want to become pregnant. Do not become pregnant for 6 months after you or your partner stop taking boceprevir.

See fact sheet 680 for more information on the side effects of pegIFN/RBV. Be sure to tell your health care provider about any side effects that you are having.

HOW DOES IT REACT WITH OTHER DRUGS?

Boceprevir with pegIFN/RBV can interact with other drugs or supplements that you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose.**

If Boceprevir is taken with boosted protease inhibitors to treat HIV, levels of both drugs are reduced. In April 2012 the FDA said that the use of Boceprevir was not recommended with ritonavir-boosted Reyataz (atazanavir), Prezista (darunavir), or Kaletra (lopinavir/ritonavir.) Other drugs to watch out for include drugs to treat high cholesterol (statins), rifampin to treat tuberculosis, drugs for erectile dysfunction, antifungal "azole" drugs, benzodiazepines and many others.

The herb **St. John's Wort** (See Fact Sheet 729) lowers the blood levels of some protease inhibitors. Do not take it while taking boceprevir.

New drug interactions are being identified all the time. Make sure that your health care provider knows about ALL drugs and supplements you are taking.

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