

a series of fact sheets written
by experts in the field of liver
disease

HCV Treatment: *Victrelis (Boceprevir)*

Alan Franciscus, Editor-in-Chief

Victrelis (*boceprevir*) is an HCV protease inhibitor that is approved by the Food and Drug Administration (FDA) in combination with pegylated interferon and ribavirin to treat adults with chronic HCV genotype.

The information in this fact sheet is taken from the FDA's document "Highlights of Prescribing Information" and Merck's press release. I will update the fact sheet as more information is released.

Treatment Naïve

The treatment protocol is a **4 week lead-in phase of pegylated interferon plus ribavirin (without Victrelis)**, followed by the triple combination of Victrelis, pegylated interferon and ribavirin.¹ Duration and continuation of treatment will be guided by the type of on-treatment response to the medications.*

All Patients—Treatment Response

The SVR or sustained virological response rates (HCV RNA negative 24 weeks after the last dose of medicine is taken) by different treatment arms are listed below:

- If HCV RNA (viral load) negative at week 8 through week 24, triple therapy was continued for a **total treatment duration of 28 weeks**; sustained virological response (SVR) = **63%** (response-guided therapy arm)
- If HCV RNA positive at week 8 but undetectable at week 24, Victrelis was stopped at week 28 and pegylated interferon/ribavirin combination therapy (without Victrelis) was continued for a **total treatment duration of 48 weeks**; SVR = **66%**

- The control arm was standard of care – pegylated interferon plus ribavirin – with a **treatment duration of 48 weeks**; SVR = **38%**

African Americans/Blacks—Treatment Response

There were also 159 African American/Black patients in the study – African Americans/Blacks comprised 15% of the patient population in this trial. The SVR rates by different treatment arms are listed below:

- If HCV RNA negative at week 8 through week 24, triple therapy was continued for a **total treatment duration of 28 weeks**; SVR = **42%** (response-guided therapy arm)
- If HCV RNA positive at week 8 but undetectable at week 24, Victrelis was stopped at week 28 and pegylated interferon/ribavirin combo therapy (without Victrelis) was continued for a **total treatment duration of 48 weeks**; SVR = **53%**
- The control arm was standard of care – pegylated interferon plus ribavirin – with a **treatment duration of 48 weeks**; SVR = **23%**

*If any patients were HCV RNA positive at week 24 all treatment was stopped.

"Treatment Failures"

The protocol consisted of a **4 week lead-in phase of pegylated interferon plus ribavirin (without Victrelis)**, followed by the triple combination of Victrelis, pegylated interferon and ribavirin and treatment duration was based on type of on-treatment response. The SVR rates and duration of treatment periods for all patients are listed below.

- If HCV RNA negative at week 8 and at week 12 the **total treatment duration was 36 weeks**; SVR = **59%** (response-guided therapy arm)
- If HCV RNA positive at week 8, but undetectable at week 12, Victrelis was stopped at week 36 and the combination of pegylated interferon/ribavirin was continued for a **total treatment duration of 48 weeks**; SVR = **66%**
- Control arm was standard of care – combination of pegylated interferon plus ribavirin – for a **total treatment duration of 48 weeks**; SVR = **21%**

*If any patients were HCV RNA positive at week 12 all treatment was stopped.

It is important to know that the treatment duration in the Victrelis containing arms were 28, 36 or 48 weeks depending on the type of on-treatment response.

The side effects in both studies were similar across all treatment arms except the following side effects were higher in the Victrelis containing arms:

- Anemia (low red blood cells) was 20 to 25% higher,
- Dysgeusia (taste changes) were 19 to 33% higher.

The discontinuation rate from all side effects was similar across arms, including the Victrelis containing arms. The use of erythropoietin (a growth factor used to treat anemia) was allowed, which may explain the low discontinuation rate due to anemia.

Quick Reference Guide:

Summary—Top Line Results:

- **Both trials included** a 4 week lead-in phase of pegylated interferon plus ribavirin (without Victrelis)
- **In the two studies**, Victrelis increased the rate of anemia, but it did not mean that more people stopped taking therapy. The use of a growth factor to control anemia was allowed. There was also an increase in dysgeusia (taste changes) reported.
- **Only people with Genotype 1 were treated – either treatment-naïve (people who had never been treated) or people who had “failed” a previous course of HCV therapy.**
- Victrelis is an HCV protease inhibitor that is **ONLY** approved in combination with pegylated interferon and ribavirin.
- Dose reductions of Victrelis are not recommended. Dose reductions for pegylated interferon and ribavirin will be based on the previous recommendations listed in the individual and combined package inserts for pegylated interferon and ribavirin.
- Pregnancy categories: Victrelis is a category B; interferon is category C; ribavirin is category X.

Treatment Naïve (never been treated):

- The 4 week lead-in was followed by the triple combination of Victrelis, pegylated interferon, ribavirin – treatment duration was guided by on-treatment response – for either 28 weeks or 48 weeks
- SVR or cure rates:
 - 63% SVR in the group of people who received a total of 28 weeks of treatment
 - 66% SVR in the group of people who received a total of 48 weeks of treatment

Treatment failure (people who failed a previous course of therapy)

- The 4 week lead-in phase was followed by the triple combination of Victrelis, pegylated interferon, ribavirin – treatment duration was guided by on-treatment response – either 36 weeks or 48 weeks
- SVR or cure rates:
 - 59% SVR in the group of people who received a total of 36 weeks of treatment
 - 66% SVR in the group of people who received a total of 48 weeks of treatment

Patient Assistance:

Merck (includes Schering-Plough subsidiary):

1-866-939-HEPC (4372)

www.merck-cares.com

For more information about hepatitis C, hepatitis B and HCV coinfections, please visit www.hcvadvocate.org.

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The information in this fact sheet is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.

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