



HCSP FACT SHEET

HCV ADVOCATE

• HCV TREATMENT: FDA-APPROVED MEDICATIONS •

Genotype 2 and 3: Sovaldi (Sofosbuvir) Plus Ribavirin Therapy

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Foreword

In December 2013, the Food and Drug Administration (FDA) approved the combination of sofosbuvir—brand name Sovaldi, plus ribavirin (RBV) to treat hepatitis C HCV genotypes 2 and 3. This fact sheet will discuss the basics of the therapy for treatment of HCV genotypes 2 and 3. For more detailed information please see the FDA approved Package Insert: *Highlights of Prescribing Information*. This fact sheet is based on the VALENCE study.

Sustained Virological Results (SVR- 12 weeks post treatment)/ Cure Rate:

- **Treatment Naïve:**
 - ◆ **Genotype 2** = 97%
 - **No cirrhosis** = 97%
 - **Cirrhosis** = 100%
 - ◆ **Genotype 3** = 93%
 - **No cirrhosis** = 93%
 - **Cirrhosis** = 92%
- **Treatment Experienced:**
 - ◆ **Genotype 2** = 90%
 - **No cirrhosis** = 91%
 - **Cirrhosis** = 88%
 - ◆ **Genotype 3** = 77%
 - **No cirrhosis** = 85%
 - **Cirrhosis** = 60%

Medications and Dose:

- Sofosbuvir (brand name Sovaldi) an HCV polymerase inhibitor. Sovaldi is a 400 mg pill taken once-a-day.
- Ribavirin (pill) taken twice daily. The dose of ribavirin is based on body weight (<75kg = 1000mg; ≥ 1000kg = 1200mg)

Dose Modification: The recommendation is that Sovaldi should not be dose reduced. If medications used with Sovaldi are discontinued—Sovaldi should also be discontinued.

HCSP FACT SHEET *A publication of the Hepatitis C Support Project*

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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.

This information is provided by the Hepatitis C Support Project a nonprofit organization for HCV education, support and advocacy

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Food Requirements:

- Sovaldi – no food requirements
- Ribavirin – taken with food

Length of Treatment:

- **Genotype 2** = 12 weeks
- **Genotype 3** = 24 weeks

Side effects: The most common side effects were fatigue and headache.

Treatment Discontinuation: The number of patients who discontinued treatment due to side effects was 1% for those who received Sovaldi plus ribavirin therapy.

Additional Indications:

- Sovaldi plus ribavirin is also approved to treat HCV in people coinfecting with HIV.
- The patients in the trial who were over 65 yo had similar cure rates as those under 65 yo—no dose adjustments were needed.

- No dose adjustment for people with mild-to-moderate kidney impairment
- No dose adjustment for people with liver impairment, but people with decompensated were not studied in the clinical trials
- People with liver cancer pre-transplant can be treated with sofosbuvir/ribavirin

Pregnancy: The prior cautions and warnings of ribavirin also apply to the combination of Sovaldi and ribavirin. The use of ribavirin can cause birth defects. Women must have a negative pregnancy test prior to therapy and partners must use at least 2 effective non-hormonal methods of birth control. A woman must have monthly pregnancy tests.

Drug-Drug Interactions: Sovaldi should not be taken with certain medications such as HIV medications, antimycobacterials and anticonvulsants. Sovaldi should not be taken with St. John’s wort (See the complete list in the *Highlights of Prescribing Information*)

Related publications:

- **Olysio (simeprevir) Package Insert** (*Highlights of Prescribing Information*)
www.hcvadvocate.org/hepatitis/factsheets_pdf/Olysio_pi.pdf
- **Sovaldi (sofosbuvir) Package Insert** (*Highlights of Prescribing Information*)
www.hcvadvocate.org/hepatitis/factsheets_pdf/sovaldi_pi.pdf
- **Patient Assistance Programs**
www.hcvadvocate.org/hepatitis/factsheets_pdf/Patient_Assistance.pdf

For more information

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| <ul style="list-style-type: none"> • American Association for the Study of Liver Diseases
 www.aasld.org • Centers for Disease Control and Prevention
 www.cdc.gov | <ul style="list-style-type: none"> • Food and Drug Administration (FDA):
 www.fda.gov • Mayo Clinic
 www.mayoclinic.com |
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