Foreword

In December 2013, the Food and Drug Administration (FDA) approved the combination of sofosbuvir—brand name Sovaldi, plus pegylated interferon and ribavirin (PEG/RBV) to treat hepatitis C (HCV) genotype 1. This fact sheet will discuss the basics of the therapy for treatment of HCV genotype 1. For more detailed information please see the Sovaldi (sofosbuvir) Package Insert. The FDA approval was based on the NEUTRINO study except where otherwise noted.

Overall the cure rates were 89% and were somewhat comparable between patients that are usually considered the ‘easiest’ to treat and those who are the most ‘difficult’ to treat (see below).

Medications and Dose:

- **Sofosbuvir** (brand name Sovaldi) a HCV polymerase inhibitor. Sovaldi is a 400 mg pill taken once-a-day.
- **Pegylated interferon** (PEG) is injected under the skin once-a-week.
- **Ribavirin** (pill) taken twice daily. The dose of ribavirin is based on body weight (<75kg = 1000mg; ≥ 100kg = 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.

Food Requirements:

- Sovaldi – no food requirements
- Ribavirin – taken with food.
- Pegylated interferon – no food requirement
Length of Treatment:
• 12 weeks

Sustained Virological Results (SVR - 12 weeks post treatment)/ Cure Rate
• Treatment Naïve: 89% overall
  ◆ Genotype 1a = 92%
  ◆ Genotype 1b = 82%
• Cirrhosis/No Cirrhosis
  ◆ No cirrhosis = 92%
  ◆ Cirrhosis = 80%
• Race
  ◆ Black = 87%*
  ◆ Non-black = 91%
*17% of trial participants were Black

Addition indications
• Sovaldi plus PEG/RBV is also approved to treat HCV in people coinfected 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 Sovaldi dose adjustment for people with mild-to-moderate kidney impairment
• No Sovaldi 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 PEG/RBV also apply to the triple combination of Sovaldi, PEG/RBV. 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 the herb—St. John’s wort. (See the complete list in the Highlights of Prescribing Information)
Genotype 1: Sovaldi (Sofosbuvir) Triple Therapy

Related publications:

- Olysio (simeprevir) Package Insert

- Sovaldi (sofosbuvir) Package Insert
  www.hcvadvocate.org/hepatitis/factsheets_pdf/sovaldi_pi.pdf

- Patient Assistance Programs
  www.hcvadvocate.org/hepatitis/factsheets_pdf/Patient_Assistance.pdf

For more information

- American Association for the Study of Liver Diseases
  www.aasld.org

- Centers for Disease Control and Prevention
  www.cdc.gov

- Food and Drug Administration (FDA):
  www.fda.gov

- Mayo Clinic
  www.mayoclinic.com

Visit our websites to learn more about viral hepatitis:

www.hcvadvocate.org • www.hbvadvocate.org
www.hepatitistattoos.org