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 4. This fact sheet will discuss the basics of the therapy for treatment of HCV genotype 4. For more detailed information please see the Sovaldi (sofosbuvir) Package Insert. The FDA approval was based on the NEUTRINO study except where otherwise noted.

Note: The NEUTRINO study included mostly patients with HCV genotype 1 (see fact sheet Genotype 1: Sovaldi (Sofosbuvir) Triple Therapy). The FDA approval for the use of the triple therapy was based on treatment of 28 HCV genotype 4 patients. The FDA Sovaldi (sofosbuvir) Package Insert information did not separate out the information between the genotypes, so I am listing out the basic information.

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; ≥ 1000kg = 1200mg).

Dose Modification:
• Sovaldi should not be dose reduced. If pegylated interferon and ribavirin are discontinued, Sovaldi should be discontinued.
Food Requirements:
- Sovaldi – no food requirement
- 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: 96% overall

Side effects
- The usual PEG/RBV side effects—fatigue, headache, nausea, insomnia and anemia.

Treatment Discontinuation
- The number of patients who discontinued treatment due to side effects was 2% for those who received Sovaldi, PEG/RBV for 12 weeks
- The NEUTRINO clinical trial only included treatment naïve patients.

Additional 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 drug dose reductions were required in this age group.

- 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 cirrhosis 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)

Note: HCV Genotype 4 is found mostly in Africa. The highest prevalence of 7.3% or 6.7 million is in Egypt. Genotype 4 accounts for 90% of the HCV infections in Egypt followed by genotype 1 at 10%. To read more about HCV in Egypt see HCV Around the World: Hepatitis C in Egypt.
**Genotype 1: Sovaldi (Sofosbuvir) Triple Therapy**

**Related publications:**

- **Olysio (simeprevir) Package Insert**

- **Sovaldi (sofosbuvir) Package Insert**

- **Patient Assistance Programs**
  [www.hcvadvocate.org/hepatitis/factsheets_pdf/Patient_Assistance.pdf](http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Patient_Assistance.pdf)

**For more information**

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