



# HCSP FACT SHEET

HCV ADVOCATE

• HCV TREATMENT: FDA-APPROVED MEDICATIONS •

## Genotype 1: Harvoni Therapy

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### Foreword

In October 2014, the Food and Drug Administration (FDA) approved the combination of sofosbuvir (polymerase inhibitor) and ledipasvir (NS5a inhibitor)—brand name Harvoni—a two drug fixed-dose combination pill in a single pill to treat hepatitis C (HCV) genotype 1. This fact sheet will discuss the basics of Harvoni therapy for treatment of HCV genotype 1. For more detailed information please see the Harvoni (sofosbuvir/ledipasvir) Full Prescribing Information. The FDA approval was based on the ION-1, 2, and 3 studies.

### Dosing:

- One pill dosed once a day

### Dose Modification:

- No dose modifications are recommended

### Food Requirements:

- Can be taken with or without food

### Length of Treatment:

- 8 weeks: Treatment-Naïve with or with cirrhosis can be considered\*
- 12 weeks: Treatment-naïve with or without cirrhosis
- 12 weeks: Treatment-experienced without cirrhosis\*\*
- 24 weeks: Treatment-experienced with cirrhosis\*\*

\*8 weeks can be considered in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL (*Note:* in the ION-3 study of Harvoni—treatment of naïve patients treated for 8 or 12 weeks with Harvoni who had an HCV RNA (viral load) of less than 6 million IU/mL—the difference in cure rate was -2.3%).



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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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\*\*Treatment-experienced patients who have failed treatment with either peginterferon alfa + ribavirin or an HCV protease inhibitor + peginterferon alfa + ribavirin).

### **Sustained Virological Results (SVR 12-weeks post treatment)**

—Cure rate listed in table below.

- Side effects
  - The most common side effects were fatigue, headache, nausea, diarrhea, and insomnia

- Treatment Discontinuation
  - In the three trials of Harvoni the treatment discontinuation rates were 0-1%

### **Additional information**

- The patients in the trial who were over 65 yo had similar cure rates to those under 65 yo—no dose adjustments were needed
- No dose adjustment for people with severe renal (kidney) impairment

<b>Genotype 1 – Harvoni</b>					
Study name/ Treatment Period	Cirrhosis	Number of Patients	Cure Rates Overall	Cure Rates Genotype 1a	Cure Rates Genotype 1b
<b>ION-1: Treatment Naïve</b>					
12 weeks	combined	212	99%	98%	100%
12 weeks	no	177	99%		
24 weeks	yes	34	94%		
<b>ION-2: Treatment Experienced*</b>					
12 weeks	combined	109	94%	95%	87%
24 weeks	combined	109	99%	99%	100%
12 weeks	no	87	95%		
24 weeks	no	86	99%		
12 weeks	yes	22	86%		
24 weeks	yes	22	100%		
<b>ION-3: Treatment Naïve</b>					
8 weeks	no	215	94%	93%	98%
12 weeks	no	216	96%	96%	98%

Gilead table adapted from: Full Prescribing Information

\*Type of Prior HCV Therapy (including PEG/RBV and protease inhibitor plus PEG/RBV)—12 weeks: 92-95%; 24 weeks: 98-100%

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### **Pregnancy**

Harvoni is pregnancy category B: There are no adequate and well controlled studies with Harvoni in pregnant women. Because animal reproduction studies are not always predictive of human response, Harvoni should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

### **Drug-Drug Interactions**

Harvoni should not be taken with certain medications such as HIV medications, antimycobacterials and anticonvulsants. Harvoni should not be taken with the herb—St. John’s wort. (See the complete list in the Full Prescribing Information.)

### *Related publications:*

- **Harvoni (sofosbuvir/ledipasvir) Full Prescribing Information**  
[http://www.hcvadvocate.org/hepatitis/factsheets\\_pdf/harvoni\\_pi.pdf](http://www.hcvadvocate.org/hepatitis/factsheets_pdf/harvoni_pi.pdf)
- **Sovaldi (sofosbuvir) Full Prescribing Information**  
[http://www.hcvadvocate.org/hepatitis/factsheets\\_pdf/sovaldi\\_pi.pdf](http://www.hcvadvocate.org/hepatitis/factsheets_pdf/sovaldi_pi.pdf)
- **Genotype 2 & 3: Sovaldi (Sofosbuvir) Plus Ribavirin**  
[www.hcvadvocate.org/hepatitis/factsheets\\_pdf/Sovaldi\\_GT2-3.pdf](http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Sovaldi_GT2-3.pdf)

### *For more information*

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