Harvoni (ledipasvir - sofosbuvir) – General Information

Approved in Canada and covered by BC’s PharmaCare

Targeted Genotype: 1

Treatment Description: Harvoni is a fixed-dose combination of ledipasvir, a NS5A inhibitor, and sofosbuvir, a nucleotide NS5B polymerase inhibitor. NS5A inhibitors block the protein NS5A that HCV needs to reproduce. Nucleotide NS5B polymerase inhibitors directly target the hep C virus to stop it from making copies of itself in the liver.

Daily Dose: 1 pill

SVR: Above 90%

Length of Treatment: 8-24 weeks

Common Side Effects: Some people in clinical trials reported side effects such as headache, fatigue, nausea, insomnia, diarrhea.

BC PharmaCare’s Eligibility for Harvoni

- Treatment is prescribed by a hepatologist, a gastroenterologist, an infectious disease specialist or other physicians experienced with treating hepatitis C; AND
- Laboratory confirmed hepatitis C genotype 1; AND
- Laboratory confirmed quantitative HCV RNA test must be done within the previous 12 months; AND
- Patient is NOT currently being treated with another hepatitis C direct-acting antiviral drug; AND
- Fibrosis stage of F2 or greater (Metavir scale or equivalent); OR

Fibrosis stage less than F2 (Metavir scale or equivalent) AND at least one of the following:

- Co-infection with HIV or hepatitis B virus
- Post organ transplant (liver and/or non-liver organ transplant)
- Extra-hepatic manifestations
- Chronic kidney disease stage 3, 4 or 5 as defined by National Kidney Foundation Kidney Disease outcomes Quality Initiative
- Co-existent liver disease with diagnosis evidence for fatty liver disease (e.g., non-alcoholic steatohepatitis)
- Diabetes receiving treatment with anti-diabetic drugs
- Women who are planning pregnancy within the next 12 months

Gilead’s Momentum Patient Assistance Program

Canadians prescribed Harvoni (ledipasvir and sofosbuvir) can request to be enrolled in the Gilead Momentum Program. For more information, contact your doctor, nurse, or call the Gilead Momentum Program at: 1-866-207-4267.

This information is meant as a resource only and is not intended to replace qualified medical attention.

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