Table 1 Recommended Treatment Duration for HARVONI in Patients with CHC Genotype 1

Patient Population	Recommended Treatment Duration
Treatment-naïve with or without cirrhosis	12 weeks*
Treatment-experienced** without cirrhosis	12 weeks
Treatment-experienced** with cirrhosis	24 weeks

* HARVONI for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL *[see Clinical Studies (14)]*.
**Treatment-experienced patients who have failed treatment with either peginterferon alfa + ribavirin or an HCV protease inhibitor + peginterferon alfa + ribavirin.

Recommended dosage: One tablet (90 mg of ledipasvir and 400 mg of sofosbuvir) taken orally once daily with or without food (2.1)

Treatment Regimen and Duration by Patient Population

Patient Population	Treatment*	Duration
Genotype 1a, without cirrhosis	VIEKIRA PAK + ribavirin	12 weeks
Genotype 1a, with cirrhosis	VIEKIRA PAK + ribavirin	24 weeks**
Genotype 1b, without cirrhosis	VIEKIRA PAK	12 weeks
Genotype 1b, with cirrhosis	VIEKIRA PAK + ribavirin	12 weeks
*Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection. **VIEKIRA PAK administered with ribavirin for 12 weeks may be considered for some patients based on prior treatment history *[See Clinical Studies (14.3)]*.		

Recommended dosage: Two ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg tablets once daily (in the morning)
and one dasabuvir 250 mg tablet twice daily (morning and evening) with a meal

without regard to fat or calorie content. (2.1)

Women: Discontinue ethinyl estradiol-containing medications such as combined oral contraceptives, contraceptive patches or contraceptive vaginal rings prior to starting Viekira Pak. Alternative contraceptive methods are recommended.

You must stop using ethinyl estradiol-containing medicines (combination birth control pills or patches, such as Lo Loestrin® FE, Norinyl®, Ortho Tri-Cyclen Lo®, Ortho Evra®; hormonal vaginal rings such as NuvaRing®; and the hormone replacement therapy medicine, Fem HRT®) before you start treatment with VIEKIRA. If you use these medicines as a method of birth control, you must use another method during treatment with VIEKIRA, and for about 2 weeks after you finish treatment with VIEKIRA.

Do not take VIEKIRA if you:

- take any of the following medicines: alfuzosin hydrochloride (Uroxatral®) • carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®) • efavirenz (Sustiva®, Atripla®) • ergot containing medicines, including ergotamine tartrate (Cafergot®, Migergot®, Ergomar®, Ergostat®, Medihaler®, Wigraine®, Wigrettes®), dihydroergotamine mesylate (D.H.E. 45®, Migranal®), methylergonovine (Ergotrate®, Methergine®) • ethinyl estradiol-containing medicines • gemfibrozil (Lopid®) • lovastatin (Advicor®, Altoprev®, Mevacor®) • midazolam (when taken by mouth) • phenytoin (Dilantin®, Phenytek®) • phenobarbital (Luminal®) • pimozide (Orap®) • rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®) • sildenafil citrate (Revatio®), when taken for pulmonary artery hypertension (PAH) • simvastatin (Zocor®, Vytorin®, Simcor®) • St. John's wort (Hypericum perforatum) or a product that contains St. John's wort • triazolam (Halcion®)
- have had a severe skin rash after taking ritonavir (Norvir®)

Dosage, Administration

Sofosfuvir 400mg orally once daily with or without food for 12 weeks *plus* **peginterferon (either peginterferon alfa-2a 180 mcg/week or alfa-2b 1.5 mcg/kg/week) in combination with ribavirin (in 2 divided doses) with food: <75 kg: 1000 mg/day or ≥75 kg: 1200 mg/day)** OR **sofosbuvir and ribavirin alone.** Treatment regimen and duration based upon patient characteristics as described in the Table below. Sofosbuvir should not be dose-reduced or used as monotherapy.

Population includes patients with or without cirrhosis as well as, HCV monoinfected or HCV/HIV-1 co-infected	**Dosage Regimens**	**Total treatment duration**
HCV Genotype 1		
Interferon-eligible	Sofosbuvir plus peginterferon and ribavirin	12 weeks
Interferon-ineligible or intolerant[a]	Sofosbuvir plus ribavirin	24 weeks
HCV Genotype 2	Sofosbuvir plus ribavirin	12 weeks
HCV Genotype 3	Sofosbuvir plus ribavirin	24 weeks
HCV Genotype 4, 5, or 6	Sofosbuvir plus peginterferon and ribavirin	12 weeks
Patients with hepatocellular carcinoma awaiting liver transplantation	Sofosbuvir plus ribavirin	Up to 48 weeks or until the time of liver transplantation

[a]**Interferon-ineligible or intolerant Genotype 1: interferon-free treatment should only be given to patients in whom interferon intolerance or ineligibility is clearly documented and who have indications for urgent antiviral therapy where the risk of delaying treatment has a high likelihood of adverse outcomes. Based on modest SVR rates in the populations studied along with the lack of data in both cirrhotics and treatment-experienced in Genotype 1, PBM recommends that sofosbuvir/ribavirin not be used. Please refer to Issues for Consideration regarding the role of simeprevir and sofosbuvir in these patients**. Interferon ineligible populations include patients with severe thrombocytopenia (platelet count <75,000/mm^3); patients with severe depression not responsive to medical therapy (documented by mental health provider); patients with decompensated liver cirrhosis (i.e., Child class B or C); patients with auto-immune diseases that may be exacerbated by interferon-mediated immune modulation.