

HEPATITIS C VIRUS TREATMENTS (Part 1 of 2)

Characteristics of Persons for Whom Therapy is Widely Accepted:

- Age ≥18yrs; Hepatitis C Virus (HCV)-RNA serum positive
- Compensated liver disease (total serum bilirubin <1.5g/dL; INR 1.5; serum albumin >3.4; platelet count 75,000/mm³; and no evidence of hepatic decompensation (hepatic encephalopathy or ascites)
- Acceptable hematological and biochemical indices: Hemoglobin 13g/dL for men and 12g/dL for women; neutrophil count 1500/mm³ and serum creatinine <1.5mg/dL

Generic	Brand	Usual Initial Dosage
DUAL THERAPY		
daclatasvir + sofosbuvir	Daklinza¹ + Sovaldi	Adults: ≥18yrs: 60mg once daily + Sovaldi 400mg once daily for 12wks. <i>Concomitant CYP3A substrates:</i> Adjust Daklinza dose to 30mg once daily (strong inhibitors) or 90mg once daily (moderate inducers). Children: <18yrs: Not established.
interferon alfa-2b + ribavirin	Intron A + Rebetol³	Adults: ≥18yrs: 3million IU SC three times weekly + Rebetal 1000mg (<75kg) or 1200mg (>75kg) in 2 divided doses for 48wks (genotype 1) or 24wks (genotype 2,3); <i>Retreatment:</i> 24wks. Children: ≥3yrs: 25–61kg: 3million IU/m ² SC three times weekly + Rebetal 15mg/kg/day in 2 divided doses for 48wks (genotype 1) or 24wks (genotype 2,3).
peginterferon alfa-2a + ribavirin	Pegasys² + Copegus³	Adults: ≥18yrs: <i>Genotype 1,4:</i> 180mcg SC once weekly + Copegus 1000mg (<75kg) or 1200mg (>75kg) in 2 divided doses for 48wks. <i>Genotype 2,3:</i> 180mcg SC once weekly + Copegus 800mg in 2 divided doses for 24wks. Children: ≥5yrs: 180mcg/1.73m ² × BSA SC once weekly + Copegus 400mg (23–33kg) or 600mg (34–46kg) or 800mg (47–59kg) or 1000mg (60–74kg) or 1200mg (>75kg) divided in AM & PM for 48wks (genotype 1,4) or 24wks (genotype 2,3); see full labeling.
peginterferon alfa-2b + ribavirin	PegIntron² + Rebetol³	Adults: ≥18yrs: 1.5mcg/kg/wk SC + Rebetal 800mg (<66kg) or 1000mg (66–80kg) or 1200mg (81–105kg) or 1400mg (>105kg) in 2 divided doses for 48wks (genotype 1) or 24wks (genotype 2,3). <i>Retreatment:</i> 48wks. <i>Prior treatment failure:</i> Add HCV NS3/4A Protease Inhibitor (unless contraindicated); treat for 48wks. Children: 3–17yrs: 60mcg/m ² /wk SC + Rebetal 15mg/kg/day in 2 divided doses for 48wks (genotype 1) or 24wks (genotype 2,3).
TRIPLE THERAPY		
simeprevir	Olysio^{4,5} + Sovaldi or peginterferon alfa & ribavirin	Adults: Take with food. 150mg once daily. <i>Genotype 1: Treatment-naïve or treatment-experienced: (without cirrhosis):</i> treat for 12wks + Sovaldi; <i>(with compensated cirrhosis [Child-Pugh A]):</i> treat for 24wks + Sovaldi. <i>Genotype 1 or 4: Treatment-naïve and prior relapsers in HCV mono-infected without cirrhosis or with compensated cirrhosis, or HCV/HIV co-infected without cirrhosis:</i> treat for 12wks + peginterferon + ribavirin, followed by additional 12wks of peginterferon + ribavirin (total 24wks). <i>Treatment-naïve and prior relapsers in HCV/HIV co-infected with compensated cirrhosis, prior non-responders (partial and null) in HCV/HIV co-infected or HCV mono-infected without cirrhosis or with compensated cirrhosis:</i> treat for 12wks + peginterferon + ribavirin, followed by additional 36wks of peginterferon + ribavirin (total 48 wks). Children: <18yrs: Not established.
sofosbuvir	Sovaldi⁴ + peginterferon alfa & ribavirin	Adults: 400mg once daily. <i>Genotype 1:</i> treat for 12wks with PegIFN alfa + RBV or 24wks with RBV if interferon-based regimen ineligible. <i>Genotype 2:</i> treat for 12wks with RBV. <i>Genotype 3:</i> treat for 24wks with RBV. <i>Genotype 4:</i> treat for 12wks with PegIFN alfa + RBV. <i>HCV/HIV-1 co-infection:</i> follow same dosage recommendations. <i>Hepatocellular carcinoma:</i> treat up to 48wks with RBV or until time of liver transplant, whichever occurs first. Children: <18yrs: Not established.
boceprevir	Victrelis⁴ + peginterferon alfa & ribavirin	Adults: Initiate peginterferon alfa + ribavirin for 4wks. Then add 800mg Victrelis three times daily to therapy. <i>Patients without cirrhosis:</i> continue treatment as indicated by HCV-RNA levels at Weeks 8, 12, and 24 (see full labeling). <i>With cirrhosis:</i> continue for 44wks. Children: <18yrs: Not established.

(continued)

HEPATITIS C VIRUS TREATMENTS (Part 2 of 2)

Generic	Brand	Usual Initial Dosage
FIXED-DOSE COMBINATION THERAPY		
elbasvir/ grazoprevir +/- ribavirin	Zepatier +/- ribavirin	<p>Adults: 1 tab once daily. <i>Genotype 1a:</i> treatment-naïve or PegIFN/RBV-experienced without baseline NS5A polymorphisms: treat for 12wks; with baseline NS5A polymorphisms: take with RBV for 16wks. <i>Genotype 1b:</i> treatment-naïve or PegIFN/RBV-experienced: treat for 12wks. <i>Genotype 1a or 1b:</i> PegIFN/RBV/HCV NS3/4A protease inhibitor-experienced: take with RBV for 12wks. <i>Genotype 4:</i> treatment-naïve: treat for 12wks; PegIFN/RBV-experienced: take with RBV for 16wks.</p> <p>Children: <18yrs: Not established.</p>
ledipasvir/sofosbuvir +/- ribavirin	Harvoni +/- ribavirin	<p>Adults: 1 tab once daily. <i>Genotype 1:</i> Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A), or treatment-experienced without cirrhosis: treat for 12wks; treatment-naïve without cirrhosis who have pre-treatment HCV RNA <6 million IU/mL: can be considered for 8wks. <i>Treatment-experienced with compensated cirrhosis:</i> treat for 24wks; can be considered for 12wks + ribavirin (if eligible). <i>Treatment-naïve and -experienced with decompensated cirrhosis (Child-Pugh B or C):</i> treat for 12wks + ribavirin (see full labeling). <i>Genotype 1 or 4:</i> <i>Treatment-naïve and -experienced liver transplant recipients without cirrhosis or with compensated cirrhosis:</i> treat for 12wks + ribavirin. <i>Genotype 4, 5, 6:</i> <i>Treatment-naïve and -experienced without cirrhosis or with compensated cirrhosis:</i> treat for 12wks. <i>HCV/HIV-1 co-infection:</i> follow same dosage schedule. See full labeling.</p> <p>Children: <18yrs: Not established.</p>
ombitasvir/ paritaprevir/ ritonavir + ribavirin	Technivie⁷ + ribavirin	<p>Adults: Take with food. ≥18yrs: 2 tabs once daily in the AM for 12wks with ribavirin. <i>Treatment-naïve (with ribavirin intolerance):</i> may consider administering without ribavirin for 12wks.</p> <p>Children: <18yrs: Not established.</p>
ombitasvir/ paritaprevir/ ritonavir + dasabuvir +/- ribavirin	Viekira Pak⁸ +/- ribavirin	<p>Adults: Take with food. Give 2 ombitasvir/paritaprevir/ritonavir tabs once daily (in AM) and 1 dasabuvir tab twice daily (AM & PM). <i>Genotype 1a without cirrhosis:</i> treat for 12wks + ribavirin. <i>Genotype 1a with compensated cirrhosis (Child-Pugh A):</i> treat for 24wks + ribavirin (12wks may be considered for some). <i>Genotype 1b with or without compensated cirrhosis:</i> treat for 12wks. <i>HCV/HIV-1 co-infection:</i> follow recommendations above. <i>Liver transplant recipients (with mild fibrosis):</i> treat for 24wks + ribavirin. In combination with ribavirin: see full labeling.</p> <p>Children: <18yrs: Not established.</p>
sofosbuvir/velpatasvir +/- ribavirin	Eclusa +/- ribavirin	<p>Adults: 1 tab once daily. <i>Without cirrhosis or with compensated cirrhosis (Child-Pugh A):</i> treat for 12wks. <i>With decompensated cirrhosis (Child-Pugh B or C):</i> treat for 12wks + ribavirin.</p> <p>Children: <18yrs: Not established.</p>

MONOTHERAPY

interferon alfa-2b	Intron A	<p>Adults: 3million IU SC or IM three times weekly for 16wks; if tolerated with normalization of ALT: continue 18–24mos (72–96wks).</p> <p>Children: Monotherapy not recommended.</p>
peginterferon alfa-2a	Pegasys^{2,5}	<p>Adults: 180mcg SC once weekly for 48wks.</p> <p>Children: Not recommended.</p>
peginterferon alfa-2b	PegIntron^{2,5}	<p>Adults: 1mcg/kg/wk SC for 1yr administered on same day of the week.</p> <p>Children: Not recommended.</p>

NOTES

Key: SVR = sustained virologic response

¹ Indicated for the treatment of chronic hepatitis C genotype 3 infection in combination with sofosbuvir only.

² Patients who fail to achieve a 2 log₁₀ drop at 12 weeks or undetectable HCV-RNA at Week 24 are highly unlikely to achieve SVR and discontinuation of therapy should be considered.

³ Ribavirin should be taken orally with food. Do not use with creatinine clearance <50mL/min. Take in 2 divided doses (AM & PM); see literature.

⁴ Indicated for the treatment of chronic hepatitis C infection for combination therapy only.

⁵ Drug is not recommended as monotherapy unless patient cannot take ribavirin as combination treatment.

⁶ Screen for HCV genotype 1a infection for NS3Q80K polymorphism prior to treatment initiation; consider alternative if Q80K polymorphism present.

⁷ Indicated for the treatment of chronic hepatitis C genotype 4 infection without cirrhosis. Contraindicated in moderate-to-severe hepatic impairment.

⁸ Indicated for the treatment of chronic HCV genotype 1a (in combination with ribavirin) or 1b infection without cirrhosis or with compensated cirrhosis. Contraindicated in moderate-to-severe hepatic impairment.

Not an inclusive list of medications, official indications and/or dosing details. For dose adjustments or reductions, please see drug monograph at www.eMPR.com and/or contact company for full drug labeling.

(Rev. 1/2017)