US Bioservices has once-daily VIEKIRA XR® in stock

Fax prescriptions to (888) 418-7246 or call (866) 223-7914

VIEKIRA XR® was approved by the U.S. Food and Drug Administration on July 25, 2016 as a once-daily, extended-release co-formulation of the active ingredients in VIEKIRA XR (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) and is for the treatment of patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection, including those with compensated cirrhosis (Child-Pugh A). VIEKIRA XR is not for people with decompensated cirrhosis.

Indication

VIEKIRA XR is indicated for the treatment of adults with chronic hepatitis C virus:

- Genotype 1a infection without cirrhosis or with compensated cirrhosis for use with ribavirin
- Genotype 1b infection without cirrhosis or with compensated cirrhosis

Table 1. Treatment Regimen and Duration by Patient Population

Patient Population	Treatment*	Duration
Genotype 1a, without cirrhosis	VIEKIRA XR + Ribavirin	12 weeks
Genotype 1a, with compensated cirrhosis (Child-Pugh A)	VIEKIRA XR + Ribavirin	24 weeks**
Genotype 1b, with or without compensated cirrhosis (Child-Pugh A)	VIEKIRA XR	12 weeks

*Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.
**VIEKIRA XR administered with ribavirin for 12 weeks may be considered for some patients based on prior treatment history.

Dosage/Administration in Adults

The recommended dosage of VIEKIRA XR is three tablets taken orally once daily. VIEKIRA XR must be taken with a meal because administration under fasting conditions may result in reduced virologic response and possible development of resistance.

Formulation	NDC	Packaging	Storage	Description
VIEKIRA XR tablets are a 4-drug fixed-dose combination of 200 mg of dasabuvir (equivalent to 216.2 mg of dasabuvir sodium monohydrate), 8.33 mg of ombitasvir, 50 mg of paritaprevir, and 33.33 mg of ritonavir.	0074-0063-28	VIEKIRA XR is dispensed in a monthly carton for a total of 28 days of therapy. Each monthly carton contains four weekly cartons. Each weekly carton contains seven daily dose packs. Each child-resistant daily dose pack contains three tablets.	Store at or below 30°C (86°F).	VIEKIRA XR tablets (dasabuvir, ombitasvir, paritaprevir, and ritonavir) are pale yellow-colored, film-coated, oblong shaped, debossed with "3QD" on one side.

Warnings and Precautions

- Risk of hepatic decompensation and hepatic failure in patients with cirrhosis
- Increased risk of ALT elevations
- Risk of HIV-1 protease inhibitor drug resistance
- Risks associated with ribavirin combination treatment

Adverse Events

- Fatigue
- Nausea
- Pruritus
- Skin reactions

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Drugs Contraindicated with Viekira XR

Drug Class	Specific Drugs Contraindicated	Clinical Comments
Alpha1-adrenoreceptor antagonist	Alfuzosin HCL	Potential for hypotension
Anti-anginal	Ranolazine	Potential for serious and/or life-threatening reactions.
Anti-arrhythmic	Dronedarone	Potential for serious and/or life-threatening reactions such as cardiac arrhythmias.
Anti-convulsants	Carbamazepine, phenytoin, phenobarbital	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of therapeutic activity of **VIEKIRA XR.**
Anti-gout	Colchicine	Potential for serious and/or life-threatening reactions in patients with renal and/or hepatic impairment.
Anti-hyperlipidemic agent	Gemfibrozil	Increase in dasabuvir exposures by 10-fold, which may increase the risk of QT prolongation.
Anti-mycobacterial	Rifampin	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of therapeutic activity of **VIEKIRA XR**.
Anti-psychotic	Lurasidone, pimozide	Potential for serious and/or life-threatening reactions; also risk for cardiac arrhythmias with pimozide.
Ergot derivatives	Ergotamine, dihydroergotamine, ergonovine, methylergonovine	Acute ergot toxicity characterized by vasospasm and tissue ischemia has been associated with co-administration of ritonavir and ergonovine, ergotamine, dihydroergotamine, or methylergonovine.
Ethinyl estradiol-containing products	Ethinyl estradiol-containing medications	Potential for ALT elevations
GI Motility Agent	Cisapride	Potential for serious and/or life threatening reactions such as cardiac arrhythmias.
Herbal Product	St. John's Wort (hypericum perforatum)	Ombitasvir, paritaprevir, ritonavir and dasabuvir exposures may decrease leading to a potential loss of therapeutic activity of **VIEKIRA XR**.
HMG-CoA Reductase Inhibitors	Lovastatin, simvastatin	Potential for myopathy, including rhabdomyolysis
Non-nucleoside reverse transcriptase inhibitor	Efavirenz	Co-administration of efavirenz-based regimens with paritaprevir, ritonavir plus dasabuvir was poorly tolerated and resulted in liver enzyme elevations
Phosphodiesterase-5 (PDE5) inhibitor	Sildenafil when dosed as Revatio for the treatment of pulmonary arterial hypertension (PAH)	Increased potential for sildenafil-associated adverse events such as visual disturbances, hypotension, priapism, and syncope
Sedatives/hypnotics	Triazolam and orally administered midazolam	Co-administration of triazolam or oral midazolam with **VIEKIRA XR** may cause large increases in the concentration of these benzodiazepines (CYP3A4 interaction). The potential exists for serious and/or life-threatening events such as prolonged or increased sedation or respiratory depression

Contraindications

If VIEKIRA XR is administered with ribavirin, the contraindications to ribavirin also apply to this combination regimen. Refer to the ribavirin prescribing information for a list of contraindications for ribavirin. VIEKIRA XR is contraindicated:

- In patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity
- With drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events
- With drugs that are moderate or strong inducers of CYP3A and strong inducers of CYP2C8 and may lead to reduced efficacy of VIEKIRA XR
- With drugs that are strong inhibitors of CYP2C8 and may increase dasabuvir plasma concentrations and the risk of QT prolongation
- In patients with known hypersensitivity to ritonavir

More Information

Abbvie Website:
www.viekirahcp.com

Prescribing Information:
www.rxabbvie.com/pdf/viekirapak_pi.pdf

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