INDICATION
VIEKIRA XR™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir) extended-release tablets are indicated for the treatment of adult patients with chronic hepatitis C virus (HCV):

• genotype 1b infection without cirrhosis or with compensated cirrhosis.
• genotype 1a infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

SAFETY CONSIDERATIONS

• Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with VIEKIRA XR. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.
• VIEKIRA XR is contraindicated: in patients with moderate to severe hepatic impairment; with certain drugs that are highly dependent on CYP3A for clearance; moderate or strong inducers of CYP3A; strong inducers and inhibitors of CYP2C8; and in patients with known hypersensitivity to ritonavir.
• When VIEKIRA XR is administered with RBV, the contraindications, warnings and precautions (particularly pregnancy avoidance), and adverse reactions for RBV also apply to this combination regimen. Refer to the RBV prescribing information.
• Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported mostly in patients with advanced cirrhosis. Monitor for clinical signs and symptoms of hepatic decompensation.
• ALT elevations >5x upper limit of normal (ULN) occurred in 1% of all subjects and were significantly more frequent in females using ethinyl estradiol-containing medications, which are contraindicated. Perform hepatic lab testing on all patients.
• Due to risk of HIV-1 protease inhibitor drug resistance, HCV/HIV-1 coinfected patients should be on a suppressive antiretroviral drug regimen.

Please see Important Safety Information, including BOXED WARNING on Hepatitis B Virus Reactivation, on page 3.
Please click here for full Prescribing Information.
1 PATIENT INFORMATION

Patient Name: ___________________________ DOB: ____________
Address (No PO Box): ______________________________
Primary Phone #: ____________________________ ALT Phone #: ____________
Shipping Preference (if eligible): ☐ Ship to Patient ☐ Ship to Provider

2 PRESCRIBER INFORMATION

Prescriber Name: ____________________________
NPI #: ________________________________
Specialty: ☐ Hepatology ☐ Gastro ☐ ID ☐ Other: ________
Address: ________________________________
Prescriber Contact Person: __________________________
Prescriber Fax #: ____________________________

3 INSURANCE INFORMATION

Please include a copy of prescription and insurance cards with this form (front and back)
☐ No Insurance Coverage
Insurance Plan: 
☐ Medicare ☐ Medicaid ☐ Private/Commercial ☐ Other
Insurance Company Name: ____________________________
Insurance Company Phone #: __________________________
Policy #: ____________________________ Group #: ____________
Policyholder Name: ____________________________ Policyholder DOB: ____________
PBM Name: ____________________________
PBM Phone #: ____________________________ PBM BIN #: ____________
PBM Group #: ____________________________

4 DIAGNOSIS AND CLINICAL INFORMATION

HCV Genotype: 1a 1b Other
Fibrosis (F) Score: 0 1 2 3 4
Treatment History:
☐ Naive ☐ Previously Treated
☐ Other Medications
Medical History:
☐ Post-liver Transplant ☐ Renal Insufficiency
☐ Proton Pump Inhibitor (PPI) Use ☐ HCV/HIV Coinfection
☐ Compensated Cirrhosis (Child-Pugh A)
Diagnosis (ICD-10 Code): ☐ B18.2 Chronic Viral Hepatitis C
☐ B19.20 Unspecified Viral Hepatitis C without Hepatic Coma
Allergies (List): ____________________________
Vaccination for Hep A and B: ☐ No ☐ Yes Year ________

5 PRESCRIPTION INFORMATION (PLEASE CHECK ONE BOX)

INDICATION | MEDICATION(S) | DOSE/STRENGTH | DIRECTIONS | QUANTITY | REFILLS
---|---|---|---|---|---
☐ GT1b NON-cirrhotic (OR) Compensated Cirrhotic (Child-Pugh A) | VIEKIRA XR | dasabuvir 200 mg, omitavir 8.33 mg, paritaprevir 50 mg, ribavirin 33.33 mg | Take three tablets once daily with a meal | 28-day supply | 

☑ GT1a NON-cirrhotic (OR) Compensated Cirrhotic (Child-Pugh A) | VIEKIRA XR | dasabuvir 200 mg, omitavir 8.33 mg, paritaprevir 50 mg, ribavirin 33.33 mg | Take three tablets once daily with a meal | 28-day supply | 

Ribavirin mg
Take _____ tabs/caps po AM and _____ tabs/caps po PM
28-day supply

By signing this form, I represent to the AbbVie Patient Assistance Program (the “Program”) that I have obtained all necessary federal and state authorizations and consents from my patient to allow me to release health information to the Program and its contracted third parties.

I verify that the information provided is current, complete, and accurate to the best of my knowledge and certify that I am authorized to receive medications at the shipping location identified in this application. I verify that my state license is currently in good standing. I further certify that I will notify the Program in writing immediately if the status of my state license number registration changes. If this applicant is eligible for the Program’s patient assistance program (the “PAP”), I understand that the Program will send the medication to the designated shipping location, which could include my office or the patient’s home. The Program reserves the right to request additional information if needed and to change or discontinue the PAP at any time, without notice. By signing this form, I certify that I am prescribing the aforementioned medication for an individual participating in the PAP. I acknowledge that I shall not seek reimbursement for any medication dispensed hereunder from any government program or third-party insurer. I also understand that the applicant’s acceptance into the PAP is not made in exchange for any explicit or implicit agreement or understanding that AbbVie Product will be used, purchased, leased, ordered, prescribed, recommended, or arranged for or provided formulary or other preferential or qualifying status. By signing this form, I authorize the Program and its representatives to transmit this prescription form electronically, by facsimile, or by mail to a pharmacy designated by the Program for the dispensing of the medication called for herein. I understand that I may not delegate signature authority. I certify that treatment with this medication is medically necessary.

Notice to Healthcare Providers and Insurers: This form of authorization may not comply with all applicable federal and state laws governing disclosure of the patient’s information to the Program and its contracted third parties. The Program urges all entities disclosing information about the patient to consult with legal counsel prior to relying on this form.

PRESCRIBER SIGNATURE – STAMP SIGNATURE NOT ALLOWED

6 X DISPENSE AS WRITTEN DATE X PRODUCT SUBSTITUTION PERMITTED DATE

Please see Important Safety Information, including BOXED WARNING on Hepatitis B Virus Reactivation, on page 3.
Please click here for full Prescribing Information or visit www.viekira.com/hcp.
INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION\(^1\)

VIEKIRA XR™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir) extended-release tablets are indicated for the treatment of adult patients with chronic hepatitis C virus (HCV):

- genotype 1b infection without cirrhosis or with compensated cirrhosis.
- genotype 1a infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

IMPORTANT SAFETY INFORMATION\(^1\)

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with VIEKIRA XR. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

Risks Associated with RBV Combination Treatment

If VIEKIRA XR is administered with RBV, the contraindications, warnings and precautions (particularly pregnancy avoidance), and adverse reactions for RBV also apply to this combination regimen. Refer to the RBV prescribing information.

CONTRAINDICATIONS

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 levels are associated with serious and/or life-threatening events; moderate or strong inducers of CYP3A and strong inhibitors of CYP2C8, which may lead to reduced efficacy of VIEKIRA XR; and strong CYP2C8 inhibitors, which may increase dasabuvir levels and the risk of QT prolongation.
- with the following drugs: afluozin HCL; ranolazine; dronedarone; carbamazepine, phenytoin, phenobarbital; colchicine (in patients with renal and/or hepatic impairment); gemfibrozil; rifampin; lurasidone, pimozide; ergotamine, dihydroergotamine, methylergonovine; ethinyl estradiol-containing medicines, such as combined oral contraceptives; cisapride; St. John’s Wort (Hypericum perforatum); atorvastatin, lovastatin, simvastatin; everolimus, sirolimus, tacrolimus; efavirenz; sildenafil (when dosed as Revatio® for pulmonary arterial hypertension); triazolam and oral midazolam.
- in patients with known hypersensitivity (e.g., toxic epidermal necrolysis or Stevens-Johnson syndrome) to ritonavir.

WARNINGS AND PRECAUTIONS

Risk of Hepatic Decompensation and Hepatic Failure in Patients with Cirrhosis
- Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported mostly in patients with advanced cirrhosis prior to initiating therapy. Reported cases typically occurred within one to four weeks of initiating therapy.
- For patients with cirrhosis: monitor for clinical signs and symptoms of hepatic decompensation; perform hepatic lab testing, including direct bilirubin levels, at baseline and during the first 4 weeks of starting treatment and as clinically indicated; discontinue treatment in patients who develop evidence of hepatic decompensation.

Increased Risk of ALT Elevation

- Elevations of ALT to >5x the upper limit of normal (ULN) occurred in 1% of all subjects in clinical trials and were significantly more frequent in females using ethinyl estradiol-containing medications. In female patients, discontinue ethinyl estradiol-containing medications prior to starting treatment and use alternative methods of contraception during therapy. Use caution when co-administering VIEKIRA XR with estrogens other than ethinyl estradiol, such as estradiol and conjugated estrogens.
- Perform hepatic lab testing on all patients during the first 4 weeks of treatment and as clinically indicated thereafter. If ALT is elevated above baseline levels, repeat testing and monitor closely. Patients should be instructed to consult their doctor without delay if they have onset of fatigue, weakness, lack of appetite, nausea and vomiting, jaundice, or discolored feces. Consider discontinuing VIEKIRA XR if ALT levels remain persistently >10x the ULN. Discontinue VIEKIRA XR if ALT elevation is accompanied by signs or symptoms of liver inflammation or increasing direct bilirubin, alkaline phosphatase, or INR.

Risk of Adverse Reactions or Reduced Therapeutic Effect Due to Drug Interactions

- The concomitant use of VIEKIRA XR and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to loss of therapeutic effect of VIEKIRA XR and possible development of resistance, or clinically significant adverse reactions from greater exposures of concomitant drugs or components of VIEKIRA XR.

HCV/HIV-1 Coinfected Patients: Risk of HIV-1 Protease Inhibitor Drug Resistance

- The ritonavir component of VIEKIRA XR is an HIV-1 protease inhibitor and can select for HIV-1 protease inhibitor resistance. To reduce this risk, HCV/HIV-1 coinfected patients should also be on a suppressive antiretroviral drug regimen.

ADVERSE REACTIONS

Most common adverse reactions observed:
- VIEKIRA XR with RBV (>10% of subjects): fatigue, nausea, pruritus, other skin reactions, insomnia, and asthenia.
- VIEKIRA XR without RBV (>5% of subjects): nausea, pruritus, and insomnia.

*Revatio® is a trademark of its respective owner and not a trademark of AbbVie Inc. The makers of this brand are not affiliated with and do not endorse AbbVie Inc. or its products.


Please click here for full Prescribing Information or visit www.viekira.com/hcp.
I understand that any assistance in the form of product at no cost is contingent upon my ability to meet the eligibility criteria for the AbbVie Patient Assistance Program ("PAP") as determined by AbbVie Inc. or third parties contracted by AbbVie Inc. in connection with the AbbVie Patient Assistance Program (collectively, "AbbVie"). I agree that AbbVie does not have any obligation to provide the PAP services to me and I waive any and all liability of AbbVie in the provision of the PAP services. I understand that by completing this form I am not guaranteed eligibility to receive medication at no cost from the PAP. In the event that I am eligible for the PAP, I acknowledge that this assistance is temporary and that I may be asked to reapply at designated intervals as determined by AbbVie. I also understand that the PAP may be changed or discontinued at any time without any notice to me and at such time the PAP services will no longer be provided. I agree that I will not seek reimbursement for any products dispensed under the PAP from any government program or third-party insurer. I certify that the information I have provided in this form is accurate and complete. I agree that I will notify the PAP if my insurance or financial situation changes. If this application has been completed by a personal representative, the personal representative warrants that it has provided a copy of this completed form to the patient.

Patient Name: ________________________________ X

PATIENT SIGNATURE / LEGAL REPRESENTATIVE (indicate relationship) ____________________________ DATE ____________________________

Please continue to page 4 for the Patient Health Insurance Portability and Accountability Act Authorization. Your signature is required.

ProCeed Nurse Connectors provide personalized treatment support to help guide you before, during, and after your treatment. A proCeed Nurse Connector does not offer medical advice or replace a conversation with a medical professional. To learn more and speak to a Nurse Connector, call 1-844-2proceed (1-844-277-6233).
PATIENT HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) AUTHORIZATION

I understand that the purpose of this authorization (“Authorization”) is to give my permission for the disclosure and use of my protected health information to the extent it is required under state and federal law.

I request and authorize my healthcare providers, healthcare insurers, pharmacies, and laboratory testing facilities that have provided treatment, payment, or services to me or for me to disclose any information regarding my health, treatment, and coverage that pertains to payment for medication to AbbVie Inc., its affiliates, or third parties contracted by AbbVie (collectively, the “Program”) for the following purposes: (i) to determine my eligibility for the Program's patient assistance program (“PAP”); (ii) if necessary, to account for and assist with my withdrawal from the PAP and/or transfer to a separate private or public payer program; (iii) to administer and maintain the high quality of the PAP; and (iv) to use certain information of mine that does not identify me to help improve, develop, and evaluate products, services, materials, programs, and treatment related to my condition or treatment, as well as for health economic outcomes research and market research. I understand that once the Program receives my health information, it may communicate with my healthcare providers and insurers to determine my PAP eligibility.

I understand that I am not required to sign this Authorization and that no healthcare provider or insurer will condition treatment, payment, enrollment, or eligibility for benefits on whether I sign this Authorization.

However, I understand that if I do not sign this Authorization, I cannot take part in the PAP (should I qualify). I understand that I may cancel this Authorization at any time by writing to the AbbVie Patient Assistance Program at P.O. Box 4280, Gaithersburg, MD 20885, as well as by notifying my healthcare providers and insurers. If I cancel this Authorization, I can no longer participate in certain aspects of the PAP. Once the Program receives and processes my cancellation request, the Program will not use my health information going forward. I understand that cancelling my Authorization will not affect any use of my health information that occurred before my request was processed. This Authorization shall be valid for 10 years from the date of the signature on this form (unless a shorter period is prescribed by state law).

I understand that, unless otherwise restricted by state law, my health information released under this Authorization is subject to redisclosure by AbbVie and AbbVie Partners and will no longer be protected by HIPAA.

In some states, the person receiving my Personal Information from making further disclosure of it, unless another authorization for such disclosure is obtained from me or unless such disclosure is required or permitted by law.

Patient Name: ________________________________  X__________________________

PATIENT SIGNATURE / LEGAL REPRESENTATIVE (indicate relationship)  DATE