

Technivie[™] (ombitasvir/paritaprevir/ritonavir) and Viekira XR[™] (dasabuvir/ombitasvir/paritaprevir/ritonavir) – Product discontinuations

- On May 22, 2018, the FDA announced the discontinuation of <u>AbbVie's Technivie</u> (ombitasvir/paritaprevir/ritonavir) and Viekira XR (dasabuvir/ombitasvir/paritaprevir/ritonavir).
 - Both product discontinuations are voluntary and due to changes in treatment practices in the current chronic HCV market in the U.S. and are not related to quality, safety or efficacy issues.
- Viekira Pak[™] (ombitasvir/paritaprevir/ritonavir with dasabuvir) will continue to be available due to reliance by countries outside the U.S. on FDA approval to support post-approval change to the label. However, Viekira Pak will not be promoted.
- <u>Viekira XR</u> and Viekira Pak 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.
 - Viekira XR is a 4-drug fixed-dose combination, extended-release tablet containing dasabuvir 200 mg, ombitasvir 8.33 mg, paritaprevir 50 mg and ritonavir 33.33 mg that is dosed once daily.
 - Viekira Pak is a 3-drug fixed dose combination tablet containing ombitasvir 12.5 mg, paritaprevir 75 mg and ritonavir 50 mg copackaged with dasabuvir 250 mg tablets. The combination tablet is taken once daily and the dasabuvir tablet is taken twice daily.
- <u>Technivie</u> is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic HCV infection without cirrhosis or with compensated cirrhosis.
- Until January 1, 2019, supply of Technivie and Viekira XR will be available for all patients who begin
 therapy prior to July 1, 2018 to ensure that they are able to complete their course of prescribed
 therapy.
- Accordingly, AbbVie advises that physicians should cease writing any new prescriptions for Viekira XR and Technivie effective July 1, 2018.
- Should a pharmacy receive a prescription for Viekira XR or Technivie after July 1, 2018 for a patient that is not already on therapy for either of these products, it is recommended that the physician be contacted to obtain a new prescription for an alternative treatment.
- Viekira XR, Viekira Pak, and Technivie carry a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients coinfected with HCV and HBV.
- Other drugs are available to treat HCV infections such as <u>Zepatier[®] (elbasvir/grazoprevir)</u>, <u>Mavyret[®] (glecaprevir/pibrentasvir)</u>, <u>Epclusa[®] (sofosbuvir/velpatasvir)</u>, <u>Harvoni[®] (ledipasvir/sofosbuvir)</u>, and Vosevi[®] (sofosbuvir/velpatasvir/voxilaprevir).

- Consult individual drug labels for specific indications.
- For additional questions, contact AbbVie at 1-800-633-9110.



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