

Ombitasvir-Paritaprevir-Ritonavir (*Technivie*)

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Drug Summary

Based on data from the PEARL-1 study, the ombitasvir-paritaprevir-ritonavir, given with ribavirin, is an effective all-oral regimen for treatment-naïve and treatment-experienced patients with genotype 4 HCV who do not have cirrhosis. At this time, the ombitasvir-paritaprevir-ritonavir regimen should only be used at this time for patients with genotype 4 HCV without cirrhosis; dasabuvir is not included in this regimen since it does not have activity against HCV genotype 4. The effectiveness of ombitasvir-paritaprevir-ritonavir in patients with genotype 4 HCV and cirrhosis is not known. Clinicians need to distinguish the ombitasvir-paritaprevir-ritonavir fixed dose medication (*Technivie*) from the closely related ombitasvir-paritaprevir-ritonavir plus dasabuvir (*Viekira Pak*); the key difference between these two is the absence of medication dasabuvir in the *Technivie* preparation.

Class and Mechanism

Ombitasvir is a NS5A inhibitor with potent pangenotypic picomolar antiviral activity and paritaprevir is an inhibitor of the NS3/4A serine protease. Ritonavir is a potent inhibitor of CYP3A4 enzymes and is used as a pharmacologic booster for paritaprevir—it significantly increases peak and trough paritaprevir plasma concentrations, as well as the area under the curve of paritaprevir. Ritonavir was originally developed and FDA-approved as an HIV protease inhibitor; it does not have activity against HCV.

Manufacturer for United States

The fixed dose combination ombitasvir-paritaprevir-ritonavir (*Technivie*) is manufactured by AbbVie. The closely related combination ombitasvir-paritaprevir-ritonavir plus dasabuvir (*Viekira Pak*) is also manufactured by AbbVie.

Cost and Medication Access

The wholesale acquisition cost (WAC) for a 12-week course of ombitasvir-paritaprevir-ritonavir is \$76,653, which corresponds to a cost per day of \$912. There are no patient assistance programs listed by AbbVie for ombitasvir-paritaprevir-ritonavir.

Adverse Effects

On October 22, 2015 the United States FDA issued a [Drug Safety Warning](#) that treatment with ombitasvir-paritaprevir-ritonavir (*Technivie*) can cause serious liver injury, mostly in patients with underlying advanced liver disease. In most of the reported cases, the liver injury occurred within 1 to 4 weeks of starting treatment. In clinical trials, approximately 1% of persons receiving ombitasvir-paritaprevir-ritonavir developed increases in alanine aminotransferase levels (ALT) to greater than 5 times the upper limit of normal. Because of this potential adverse effect, patients should have hepatic laboratory testing during the first 4 weeks after starting therapy, with further monitoring thereafter as clinically indicated. Among the 135 patients with genotype 4 HCV treated with ombitasvir-paritaprevir-ritonavir, none developed serum ALT levels greater than 5 times the upper limit of normal. The most common adverse effects observed in the PEARL-1 trial for patients receiving ombitasvir-paritaprevir-ritonavir without ribavirin were asthenia (25%), nausea (9%), and fatigue (7%).

Key Drug Interactions

Drug interactions with ombitasvir-paritaprevir-ritonavir are complex and the number of potential drug-drug interactions are extensive. Thus, see the Full Prescribing Information for detailed information and detailed tables regarding drug interactions with ombitasvir-paritaprevir-ritonavir. The following summarizes the major conceptual drug-drug interactions with ombitasvir-paritaprevir-ritonavir.

- Potential for Ombitasvir-Paritaprevir-Ritonavir to Affect other Drugs: Ritonavir is a potent inhibitor of CYP3A4 and an inhibitor of BCRP and P-gp. Paritaprevir is an inhibitor of OATP1B1 and OATP1B3, BCRP, and P-gp. Thus, administration of ombitasvir-paritaprevir-ritonavir with other medications that are substrates of CYP3A4, P-gp, BCRP, OATP1B1, or OATP1B3 could cause an increase in the plasma concentrations of these other medications.
- Potential for Other Medications to Impact Levels of Ombitasvir, Paritaprevir, or Ritonavir: The primary route for ombitasvir metabolism occurs through amide hydrolysis. The medications ritonavir and paritaprevir are metabolized primarily via the CYP3A enzymes and thus coadministration with strong inhibitors of CYP3A can potentially increase paritaprevir and ritonavir plasma concentrations. All three medications are substrates of P-gp. Paritaprevir is also a substrate of BCRP, OATP1B1, and OATP1B3. Medications that act as inhibitors of P-gp, BCRP, OATP1B1, or OATP1B3 can potentially increase levels of one or more of the medications in the ombitasvir-paritaprevir-ritonavir regimen.

For complete information on ombitasvir-paritaprevir-ritonavir-related drug interactions, see the [Drug Interactions section in the Ombitasvir-Paritaprevir-Ritonavir \(*Technivie*\) Prescribing Information](#).

Figures

Figure 1 Monthly Supply Carton

Ombitasvir-Paritaprevir-Ritonavir

Photograph courtesy of AbbVie, Inc.



Figure 2 1 Week Supply Carton

Ombitasvir-Paritaprevir-Ritonavir

Photograph courtesy of AbbVie, Inc.



Figure 3 Daily-Dose Pack

Ombitasvir-Paritaprevir-Ritonavir

Photograph courtesy of AbbVie, Inc.

