

```
var drug_url = "ombitasvir-paritaprevir-ritonavir";
```



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-naive 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

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

Clinical Trials

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PEARL-I

In the phase 2b PEARL-I study, patients with chronic genotype 4 HCV infection, without cirrhosis, were treated with a 12-week course of ombitasvir plus paritaprevir plus ritonavir, with or without ribavirin. The study was a multicenter trial conducted in Europe, Turkey, and the United States. The enrollment included treatment-naive and treatment-experienced patients. The treatment-naive patients were randomized to receive a regimen with or without ribavirin, whereas all treatment-experienced patients received a regimen that included ribavirin. Note the regimen used in this trial did not include dasabuvir since it does not have activity against genotype 4 HCV. For the treatment-naive patients, 40 (91%) of 44 achieved an SVR12 with the regimen ombitasvir plus paritaprevir plus ritonavir; 42 (100%) of 42 of the treatment-naive patients achieved an SVR with ombitasvir plus paritaprevir plus ritonavir and ribavirin. Among the treatment-experienced patients, 49 (100%) of 49 patients achieved an SVR12 with ombitasvir plus paritaprevir plus ritonavir and ribavirin. This regimen was well-tolerated and there were few treatment discontinuations.

View Clinical Trial: [In your Browser](#) | [Download PDF](#)

References

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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.

