HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TECHNIVIE safely and effectively. See full prescribing information for TECHNIVIE.

TECHNIVIE (ombitasvir, paritaprevir and ritonavir) tablets, for oral use
Initial U.S. Approval: 2015

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV
See full prescribing information for complete boxed warning.

Hepatitis B virus (HBV) reactivation has been reported, in some cases resulting in fulminant hepatitis, hepatic failure, and death. (5.1)

RECENT MAJOR CHANGES

Boxed Warning	2/2017
Dosage and Administration (2.1)	2/2017
Contraindications (4)	5/2016
Warnings and Precautions (5.1)	2/2017

INDICATIONS AND USAGE
TECHNIVIE is a fixed-dose combination of ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor and is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis. (1)

DOSAGE AND ADMINISTRATION
Testing Prior to the Initiation of Therapy:
- Test all patients for HBV infection by measuring HBsAg and anti-HBc. (2.1)
- Assess baseline hepatic laboratory and clinical parameters. (2.1)

Recommended dosage: Two tablets taken orally once daily (in the morning) with a meal without regard to fat or calorie content. TECHNIVIE is recommended to be used in combination with ribavirin. (2.2)

Patient Population	Treatment	Duration
Genotype 4 without cirrhosis	TECHNIVIE + ribavirin*	12 weeks
*TECHNIVIE administered without ribavirin for 12 weeks may be considered for treatment-naïve patients who cannot take or tolerate ribavirin *[see Microbiology (12.4) and Clinical Studies (14)]*.		

DOSAGE FORMS AND STRENGTHS
Tablets: 12.5 mg ombitasvir, 75 mg paritaprevir, 50 mg ritonavir. (3)

CONTRAINDICATIONS
- The contraindications to ribavirin also apply to this combination regimen. (4)
- Patients with moderate to severe hepatic impairment. (4, 5.2, 8.6, 12.3)
- Co-administration with drugs that are: highly dependent on CYP3A for clearance; moderate and strong inducers of CYP3A. (4)
- Known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome). (4)

WARNINGS AND PRECAUTIONS
- Risk of Hepatitis B Virus Reactivation: Test all patients for evidence of current or prior HBV infection before initiation of HCV treatment. Monitor HCV/HBV coinfected patients for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated. (5.1)
- Hepatic Decompensation and Hepatic Failure in Patient with Cirrhosis: Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported mostly in patients with advanced cirrhosis. Discontinue treatment in patients who develop evidence of hepatic decompensation. (5.2)
- ALT Elevations: Discontinue ethinyl estradiol-containing medications prior to starting TECHNIVIE (alternative contraceptive methods are recommended). Perform hepatic laboratory testing on all patients during the first 4 weeks of treatment. For ALT elevations on TECHNIVIE, monitor closely and follow recommendations in full prescribing information. (5.3)
- Risks Associated With Ribavirin Combination Treatment: The warnings and precautions for ribavirin also apply to this combination regimen. (5.4)
- Drug Interactions: The concomitant use of TECHNIVIE and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to loss of therapeutic effect of TECHNIVIE. (5.5)

ADVERSE REACTIONS
The most commonly reported adverse reactions (incidence greater than 10% of subjects, all grades) observed with treatment with ombitasvir, paritaprevir and ritonavir with ribavirin for 12 weeks were asthenia, fatigue, nausea and insomnia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact AbbVie Inc. at 1-800-633-9110 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
Co-administration of TECHNIVIE can alter the plasma concentrations of some drugs and some drugs may alter the plasma concentrations of TECHNIVIE. The potential for drug-drug interactions must be considered before and during treatment. Consult the full prescribing information prior to and during treatment for potential drug interactions. (4, 5.5, 7, 12.3)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 2/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

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 TECHNIVIE. 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 *[see Warnings and Precautions (5.1)]*.

1 INDICATIONS AND USAGE

TECHNIVIE is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis.

2 DOSAGE AND ADMINISTRATION

2.1 Testing Prior to the Initiation of Therapy

- Test all patients for evidence of current or prior HBV infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment with TECHNIVIE *[see Warnings and Precautions (5.1)]*.
- Prior to initiation of TECHNIVIE, assess baseline hepatic laboratory and clinical parameters *[see Contraindications (4) and Warnings and Precautions (5.2 and 5.3)]*.

2.2 Recommended Dosage in Adults

TECHNIVIE is ombitasvir, paritaprevir and ritonavir fixed dose combination tablets.

The recommended dosage of TECHNIVIE is two tablets taken orally once daily (in the morning). Take TECHNIVIE with a meal without regard to fat or calorie content *[see Clinical Pharmacology (12.3)]*.

TECHNIVIE is used in combination with ribavirin (RBV). When administered with TECHNIVIE, the recommended dosage of RBV is based on weight: 1000 mg per day for subjects less than 75 kg and 1200 mg per day for those weighing at least 75 kg, divided and administered twice-daily with food. For ribavirin dosage modifications, refer to the ribavirin prescribing information.

Table 1 shows the recommended TECHNIVIE treatment regimen and duration for HCV genotype 4 patients without cirrhosis.

Table 1. Treatment Regimen and Duration for Patients with HCV Genotype 4 without Cirrhosis

Patient Population	Treatment	Duration
Genotype 4 without cirrhosis	TECHNIVIE + ribavirin*	12 weeks
*TECHNIVIE administered without RBV for 12 weeks may be considered for treatment-naïve patients who cannot take or tolerate ribavirin *[see Microbiology (12.4) and Clinical Studies (14)]*.		

2.3 Dosage in Patients with Hepatic Impairment

TECHNIVIE is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh B and C) *[see Contraindications (4), Warnings and Precautions (5.2), Use in Specific Populations (8.6), and Clinical Pharmacology (12.3)]*.

3 DOSAGE FORMS AND STRENGTHS

TECHNIVIE is a pink-colored, film-coated, oblong, biconvex-shaped tablet debossed “AV1” on one side. Each tablet contains 12.5 mg ombitasvir, 75 mg paritaprevir and 50 mg ritonavir.

4 CONTRAINDICATIONS

- The contraindications to ribavirin also apply to this combination regimen. Refer to the ribavirin prescribing information for a list of contraindications for ribavirin.
- TECHNIVIE is contraindicated:
  - In patients with moderate to severe hepatic impairment (Child-Pugh B and C) due to risk of potential toxicity *[see Warnings and Precautions (5.2), Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)]*.
  - 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 may lead to reduced efficacy of TECHNIVIE.
  - In patients with known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome).

Table 2 lists drugs that are contraindicated with TECHNIVIE *[see Drug Interactions (7)]*.

Table 2. Drugs that are Contraindicated with TECHNIVIE

Drug Class	Drug(s) within Class that are Contraindicated	Clinical Comments
Alpha1-adrenoreceptor antagonist	Alfuzosin HCl	Potential for hypotension.
Anti-gout	Colchicine	Potential for serious and/or life-threatening reactions in patients with renal and/or hepatic

		impairment.
Anti-anginal	Ranolazine	Potential for serious and/or life-threatening reactions.
Antiarrhythmic	Dronedarone	Potential for serious and/or life-threatening reactions such as cardiac arrhythmias.
Anticonvulsants	Carbamazepine, phenytoin, phenobarbital	Ombitasvir, paritaprevir and ritonavir exposures may decrease leading to a potential loss of therapeutic activity of TECHNIVIE.
Antimycobacterial	Rifampin	Ombitasvir, paritaprevir and ritonavir exposures may decrease leading to a potential loss of therapeutic activity of TECHNIVIE.
Antipsychotic	Lurasidone Pimozide	Potential for serious and/or life-threatening reactions. Potential for serious and/or life-threatening reactions such as cardiac arrhythmias.
Ergot derivatives	Ergotamine, dihydroergotamine, 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 such as combined oral contraceptives	Potential for ALT elevations *[see Warnings and Precautions (5.3)]*.
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 and ritonavir exposures may decrease leading to a potential loss of therapeutic activity of TECHNIVIE.
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 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)	There is increased potential for sildenafil-associated adverse events such as visual disturbances, hypotension, priapism, and syncope.
Sedatives/hypnotics	Triazolam Orally administered midazolam	Triazolam and orally administered midazolam are extensively metabolized by CYP3A4. Coadministration of triazolam or orally

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