

without delay if such symptoms occur [see *Warnings and Precautions (5.1 and 5.2) and Adverse Reactions (6.1)*].

Pregnancy

Advise patients to avoid pregnancy during treatment with TECHNIVIE with ribavirin. Inform patients to notify their health care provider immediately in the event of a pregnancy [see *Use in Specific Populations (8.1)*].

Drug Interactions

Inform patients that TECHNIVIE may interact with some drugs; therefore, patients should be advised to report to their healthcare provider the use of any prescription, non-prescription medication or herbal products [see *Contraindications (4), Warnings and Precautions (5.4) and Drug Interactions (7)*].

Inform patients that contraceptives containing ethinyl estradiol are contraindicated with TECHNIVIE [see *Contraindications (4) and Warnings and Precautions (5.2)*].

Hepatitis C Virus Transmission

Inform patients that the effect of treatment of hepatitis C virus infection on transmission is not known, and that appropriate precautions to prevent transmission of the hepatitis C virus during treatment should be taken.

Missed Dose

Inform patients that in case a dose of TECHNIVIE is missed, the prescribed dose can be taken within 12 hours.

If more than 12 hours has passed since TECHNIVIE is usually taken, the missed dose should NOT be taken and the patient should take the next dose as per the usual dosing schedule.

Instruct patients not to take more than their prescribed dose of TECHNIVIE to make up for a missed dose.

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MEDICATION GUIDE TECHNIVIE (TEK-ni-vee) (ombitasvir, paritaprevir and ritonavir tablets)
Important information: TECHNIVIE is taken in combination with ribavirin. You should also read the Medication Guide that comes with ribavirin.
What is the most important information I should know about TECHNIVIE? TECHNIVIE may cause severe liver problems, especially in people with certain types of cirrhosis. These severe liver problems can lead to the need for a liver transplant, or can lead to death.

TECHNIVIE can cause increases in your liver function blood test results, especially if you use ethinyl estradiol-containing medicines (such as some birth control products).

- You must stop using ethinyl estradiol-containing medicines before you start treatment with TECHNIVIE. See the section “**Who should not take TECHNIVIE?**” for a list of these medicines.
- If you use these medicines as a method of birth control, you must use another method of birth control during treatment with TECHNIVIE, and for about **2** weeks after you finish treatment with TECHNIVIE. Your healthcare provider will tell you when you may begin taking ethinyl estradiol-containing medicines.
- Your healthcare provider should do blood tests to check your liver function during the first 4 weeks and then as needed, during treatment with TECHNIVIE.
- Your healthcare provider may tell you to stop taking TECHNIVIE if you develop signs or symptoms of liver problems.
- Tell your healthcare provider right away if you develop any of the following symptoms, or if they worsen during treatment with TECHNIVIE:
 - tiredness
 - weakness
 - loss of appetite
 - nausea and vomiting
 - yellowing of your skin or eyes
 - color changes in your stools
 - confusion
 - swelling of the stomach area

What is TECHNIVIE?

- TECHNIVIE is a prescription medicine used with ribavirin to treat people with genotype 4 chronic (lasting a long time) hepatitis C virus (HCV) infection without cirrhosis. You should also read the Medication Guide for ribavirin.
- TECHNIVIE is not for people with certain types of liver problems.
- Each TECHNIVIE tablet contains the medicines ombitasvir, paritaprevir and ritonavir.

It is not known if TECHNIVIE is safe and effective in children under 18 years of age.

Who should not take TECHNIVIE?

Do not take TECHNIVIE if you:

- **have severe liver problems**
- **take any of the following medicines:**
 - alfuzosin hydrochloride (Uroxatral[®])
 - carbamazepine (Carbatrol[®], Epitol[®], Equetro[®], Tegretol[®])

- colchicine (Colcrys[®])
 - efavirenz (Atripla[®], Sustiva[®])
 - ergot containing medicines including:
 - ergotamine tartrate (Cafergot[®], Ergomar[®], Ergostat[®], Medihaler[®], Migergot[®], Wigraine[®], Wigrettes[®])
 - dihydroergotamine mesylate (D.H.E. 45[®], Migranal[®])
 - methylergonovine (Ergotrate[®], Methergine[®])
 - ethinyl estradiol-containing medicines:
 - combination birth control pills or patches, such as Lo Loestrin[®] FE, Norinyl[®], Ortho Tri-Cyclen Lo[®], Ortho Evra[®]
 - hormonal vaginal rings such as NuvaRing[®]
 - the hormone replacement therapy medicine, Fem HRT[®]
 - lovastatin (Advicor[®], Altoprev[®], Mevacor[®])
 - midazolam, when taken by mouth
 - phenytoin, (Dilantin[®], Phenytek[®])
 - phenobarbital (Luminal[®])
 - pimozide (Orap[®])
 - rifampin (Rifadin[®], Rifamate[®], Rifater[®] Rimactane[®])
 - sildenafil citrate (Revatio[®]), when taken for pulmonary artery hypertension (PAH)
 - simvastatin (Simcor[®], Vytorin[®], Zocor[®])
 - St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
 - triazolam (Halcion[®])
- **have had a severe skin rash after taking ritonavir (Norvir[®])**

Before taking TECHNIVIE tell your healthcare provider about all your medical conditions, including if you:

- have liver problems other than hepatitis C infection. **See “Who should not take TECHNIVIE?”**
- have HIV infection
- have had a liver transplant. If you take the medicines tacrolimus (Prograf[®]) or cyclosporine (Gengraf[®], Neoral[®], Sandimmune[®]) to help prevent rejection of your transplanted liver, the amount of these medicines in your blood may increase during treatment with TECHNIVIE.

- Your healthcare provider should check the level of tacrolimus or cyclosporine in your blood, and if needed may change your dose of these medicines or how often you take them.
- When you finish taking TECHNIVIE or if you have to stop TECHNIVIE for any reason, your healthcare provider should tell you what dose of tacrolimus or cyclosporine to take and how often you should take it.
- are pregnant or plan to become pregnant. It is not known if TECHNIVIE will harm your unborn baby. **When taking TECHNIVIE in combination with ribavirin you should also read the ribavirin Medication Guide for important pregnancy information.**
- are breastfeeding or plan to breastfeed. It is not known if TECHNIVIE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take TECHNIVIE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with TECHNIVIE. **Keep a list of your medicines to show your healthcare provider and pharmacist.**

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with TECHNIVIE.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take TECHNIVIE with other medicines.
- When you finish treatment with TECHNIVIE:
 - If your healthcare provider changed the dose of one of your usual medicines during treatment with TECHNIVIE: Ask your healthcare provider about when you should change back to your original dose after you finish treatment with TECHNIVIE.
 - If your healthcare provider told you to stop taking one of your usual medicines during treatment with TECHNIVIE: Ask your healthcare provider if you should start taking these medicines again after you finished treatment with TECHNIVIE.

How should I take TECHNIVIE?

- Take TECHNIVIE exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to.
- Do not stop taking TECHNIVIE without first talking with your healthcare provider.
- Take 2 TECHNIVIE tablets every day in the morning, with a meal.
- If you take too much TECHNIVIE, call your healthcare provider or go to the nearest emergency room right away.
- TECHNIVIE is supplied in **monthly cartons that contain enough medicine for 28 days.**
 - Each monthly carton of TECHNIVIE contains **4 smaller cartons.**
 - Each of the 4 smaller cartons contains enough child resistant **daily dose packs** of medicine to last for **7 days (1 week).**
 - Each **daily dose pack** contains all of your TECHNIVIE medicine for **1 day (2 tablets).**

- Follow the instructions on each daily dose pack about how to remove the tablets.
- If you miss a dose of TECHNIVIE tablets, and it is **less than 12 hours** from the time you usually take your dose, **take the missed dose** with a meal as soon as possible. Then take your next dose at your usual time with a meal.
- If you miss a dose of TECHNIVIE tablets, and it is **more than 12 hours** from the time you usually take your dose, **skip the missed dose**. Then take your next dose at your usual time with a meal.
- Do not take more than your prescribed dose of TECHNIVIE to make up for a missed dose.

What are the possible side effects of TECHNIVIE?

TECHNIVIE can cause serious side effects. See “What is the most important information I should know about TECHNIVIE?”

Common side effects of TECHNIVIE when used with ribavirin include:

- feeling weak
- nausea
- tiredness
- sleep problems

These are not all the possible side effects of TECHNIVIE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TECHNIVIE?

- Store TECHNIVIE at or below 86°F (30°C).

Keep TECHNIVIE and all medicines out of the reach of children.

General information about the safe and effective use of TECHNIVIE

It is not known if treatment with TECHNIVIE will prevent you from infecting another person with the hepatitis C virus during your treatment. Talk with your healthcare provider about ways to prevent spreading the hepatitis C virus.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TECHNIVIE for a condition for which it was not prescribed. Do not give TECHNIVIE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TECHNIVIE that is written for health professionals.

What are the ingredients in TECHNIVIE?

Active ingredients: ombitasvir, paritaprevir, and ritonavir

Inactive ingredients: copovidone, K value 28, vitamin E polyethylene glycol succinate, propylene glycol monolaurate Type I, sorbitan monolaurate, colloidal silicon dioxide/colloidal anhydrous silica, sodium stearyl fumarate, polyvinyl alcohol, polyethylene glycol 3350/macrogol 3350, talc, titanium dioxide, and red iron oxide.

Manufactured by AbbVie Inc., North Chicago, IL 60064.

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www.technivie.com or call 1-844-283-2464.

This Medication Guide has been approved by the U.S. Food and Drug Administration.
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