

MEDICATION GUIDE
TECHNIVIE (TEK-ni-vee)
(ombitasvir, paritaprevir and ritonavir tablets)

Important: 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 can cause serious side effects, including:

- **Hepatitis B virus reactivation:** Before starting treatment with TECHNIVIE, your healthcare provider will do blood tests to check for hepatitis B virus infection. If you have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment for hepatitis C virus with TECHNIVIE. Hepatitis B virus that becomes active again (called reactivation) may cause serious liver problems including liver failure and death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking TECHNIVIE.
- **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. If you have cirrhosis, your healthcare provider will check your liver before and during treatment with TECHNIVIE.
- **Increases in your liver function blood tests**, especially if you use ethinyl estradiol-containing medicines (contained in certain birth control products).
 - You must stop using ethinyl estradiol-containing medicines before you start treatment with TECHNIVIE. See the section “**Do not take TECHNIVIE if you**” 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 | • yellowing of your skin or eyes |
| • weakness | • color changes in your stools |
| • loss of appetite | • confusion |
| • nausea and vomiting | • swelling of the stomach area |

For more information about side effects, see the section “What are the possible side effects of TECHNIVIE?”

What is TECHNIVIE?

TECHNIVIE is a prescription medicine used with ribavirin to treat adults with genotype 4 chronic (lasting a long time) hepatitis C virus (HCV) infection without cirrhosis or with a certain type of cirrhosis (compensated). You should also read the Medication Guide for ribavirin.

TECHNIVIE can be used in people who have compensated cirrhosis.

TECHNIVIE is not for people with advanced cirrhosis (decompensated). If you have cirrhosis, talk to your healthcare provider before taking TECHNIVIE.

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.

Do not take TECHNIVIE if you:

- have moderate or severe liver problems
- take any of the following medicines:
 - alfuzosin hydrochloride
 - atorvastatin

- carbamazepine
 - cisapride
 - colchicine in people who have certain kidney or liver problems
 - dronedarone
 - efavirenz
 - ergot containing medicines including:
 - ergotamine
 - dihydroergotamine
 - methylergonovine
 - ethinyl estradiol-containing medicines:
 - combination birth control pills or transdermal systems
 - hormonal vaginal rings
 - the hormone replacement therapy
 - everolimus
 - lovastatin
 - lurasidone
 - midazolam, when taken by mouth
 - phenytoin
 - phenobarbital
 - pimozone
 - ranolazine
 - rifampin
 - sildenafil citrate when taken for pulmonary artery hypertension (PAH)
 - simvastatin
 - sirolimus
 - St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
 - tacrolimus
 - triazolam
- have had a severe skin rash after taking ritonavir

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

- have had hepatitis B virus infection
- have liver problems other than hepatitis C infection
- have HIV-1 infection
- have had a liver transplant. If you take cyclosporine to help prevent rejection of your transplanted liver, the amount of this medicine in your blood may increase during treatment with TECHNIVIE.
 - Your healthcare provider should check the level of cyclosporine in your blood, and if needed may change your dose or how often you take it.
 - When you finish taking TECHNIVIE or if you have to stop TECHNIVIE for any reason, your healthcare provider should tell you what dose of 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. You or your partner must take extreme care not to become pregnant during treatment with TECHNIVIE with ribavirin and for 6 months after stopping ribavirin. Tell your healthcare provider right away if you or your partner become pregnant. **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.

- 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.
- Do not stop taking TECHNIVIE without first talking with your healthcare provider.
- Take 2 TECHNIVIE tablets every day, with a meal.
- TECHNIVIE comes 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 **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 child resistant daily dose pack about how to remove the tablets.
- It is important that you do not miss or skip doses of TECHNIVIE during treatment.
- If you take too much TECHNIVIE, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of TECHNIVIE?

TECHNIVIE can cause serious side effects, including:

See “What is the most important information I should know about TECHNIVIE?”

Common side effects of TECHNIVIE when used with ribavirin include:

- feeling weak
- tiredness
- headache
- change in mood
- itching
- nausea
- sleep problems
- trouble breathing
- muscle or joint pain
- skin reactions
- dizziness

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). Do not remove tablets from the daily dose pack until you are ready to take them.

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

General information about the safe and effective use of TECHNIVIE

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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For more information, go to 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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