

Technivie (ombitasvir/ paritaprevir/ ritonavir)

Summary

Technivie is a medication used to treat hepatitis C. It is approved in Canada for people with genotype 4 virus. Technivie is a combination of three drugs—the antivirals ombitasvir and paritaprevir with a small dose of ritonavir (Norvir)—that are co-formulated into one tablet. The dosing for this medication is two tablets taken once a day with food. Technivie is prescribed with ribavirin. Technivie appears to have few side effects. Common side effects, which include fatigue, headache and weakness, are generally mild and temporary. Hepatitis C treatment can cure a person from hepatitis C. However, a person could become infected again.

What is Technivie?

Technivie is a medication used to treat hepatitis C.

How does Technivie work?

Hepatitis C virus is a disease that can injure the liver. A virus is a very tiny germ that infects a cell and causes the cell to make copies of the virus in a process called replication. The hepatitis C virus has at least seven different strains, which are also known as genotypes.

Technivie is a combination of direct-acting antiviral (DAA) medications, a group of drugs that directly attack the ability of a specific virus, such as hepatitis C, to make copies of itself.

FACT SHEET

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Technivie is a combination of two DAAs:

- paritaprevir – a protease inhibitor that is boosted with ritonavir
- ombitasvir – an NS5A inhibitor

Paritaprevir works by interfering with the production of the pieces needed to build new virus particles. Ritonavir is used as a booster to raise and maintain levels of paritaprevir in the blood. Ombitasvir works by interfering with a protein needed to make new copies of the hepatitis C virus. These medications work together to stop new viruses from being made.

Ribavirin is a medication that when taken with other DAAs can make a powerful combination. However, it is not well understood how it works.

Hepatitis C treatment can cure a person from hepatitis C infection and can lessen the likelihood of further health issues, such as liver failure and liver cancer.

Being cured of hepatitis C does not protect a person from being reinfected in the future. For more information on preventing hepatitis C from passing from person to person, see Prevention and Harm Reduction in CATIE's *Hepatitis C: An in-depth guide* at www.catie.ca.

How do people use Technivie?

Technivie is one tablet that is a co-formulation of ombitasvir and paritaprevir boosted with ritonavir.

The following table shows when to take the tablets and how many to take:

Tablet name	Time of day it is taken	How many
Technivie	morning	2 tablets

Technivie should be taken with food, but it does not matter what kind of food.

Technivie is taken with ribavirin. Your doctor will tell you how many ribavirin tablets to take and when to take them.

Technivie is approved in Canada for people with genotype 4 hepatitis C virus, who:

- do not have advanced liver injury (cirrhosis)
- have never been treated, or
- who have been treated with peg-interferon and ribavirin and were not cured

How long is treatment?

The majority of people take Technivie with ribavirin for 12 weeks.

Sticking to treatment

All medications work best when they are taken exactly as prescribed and directed. This means taking the medications in the right amount and at the right time for the entire length of time that your treatment lasts. Skipping doses or stopping treatment altogether means that the treatment may not work as well and the chance of being cured is lower.

With some hepatitis C medications, there is a chance that the virus can become resistant to the medication if it is not taken as prescribed and directed. In this case, the medication will not be effective against the virus and can no longer be used to treat the infection. (See the "Resistance" section to learn about the potential for resistance to the medications in Technivie.)

What can you do if you forget to take your medication?

If you miss taking a dose of Technivie and it is within 12 hours of when you were supposed to take it, take it as soon as possible. If it is after 12 hours from when you were supposed to take it, wait and take the next dose at your regular time. Do not take a double dose.

If you find that you are not able to take your medication as prescribed and directed, talk to your nurse or doctor right away. You can also check out the section "Tips for staying on track with treatment" in CATIE's *Hepatitis C: An in-depth guide* at www.catie.ca.

How likely is a cure from treatment that includes Technivie?

Treatment with DAAs can usually cure a person from hepatitis C.

In late-stage clinical trials of Technivie with ribavirin, participants had approximately the following cure rates:

People with virus genotype	Cure rate
genotype 4	100%

Sometimes in real life the cure rates can be lower than in clinical trials.

A cure for hepatitis C is also known as a sustained virological response (SVR). This is when the hepatitis C virus is no longer detected in the blood 12 or more weeks after treatment ends.

Warnings

1. Combination therapy

Technivie must be taken in combination with ribavirin, so all of the warnings that apply to ribavirin also apply to people considering Technivie. For more information on ribavirin, see the ribavirin factsheet.

2. Pregnancy

Ribavirin can harm a fetus and the drugs in Technivie have not been tested in people who are pregnant, so these medications should not be taken by anyone who is pregnant. Talk to your doctor if you are pregnant or thinking about having a baby.

People on hepatitis C treatment who could get pregnant or who are sex partners with someone who could get pregnant should use two forms of reliable contraception.

3. Breastfeeding/nursing

People with infants who are taking Technivie should not breastfeed or nurse their children.

4. Hepatitis B virus

The U.S. Food and Drug Administration (FDA) recommends that all people starting hepatitis C treatment with direct-acting antiviral (DAA) medications be tested for hepatitis B before starting treatment.

This is because if someone is co-infected with hepatitis C and hepatitis B and is not receiving treatment for hepatitis B, treatment with DAAs could reactivate hepatitis B during or after treatment. For more information about being tested for hepatitis B, speak to your doctor or nurse.

5. Special populations

People who should not be treated with Technivie:

- people with hepatitis C genotypes other than genotype 4
- people under the age of 18
- people who have severe liver damage (Child-Pugh Class B or C¹)
- people who have previously taken Technivie or other DAAs
- people who have a hypersensitivity to ritonavir

Groups of people for whom there is limited or no information about the effectiveness of Technivie:

- people who have previously taken other DAAs and were not cured
- people who are co-infected with hepatitis B virus
- people who have had a liver transplant
- people on kidney dialysis
- people who are co-infected with HIV

In a late-stage trial of Technivie and ribavirin in 28 people co-infected with hepatitis C and HIV, cure rates were 96%. Participants received 12 or 24 weeks of treatment.

1. Child-Pugh Class A, B and C are assessments of the severity of cirrhosis and a person's likelihood of survival. Child-Pugh B and C are more severe forms of cirrhosis.

If you are in one of the groups for which there is limited or no information, the risks and benefits of taking Technivie need to be carefully weighed, so speak to your doctor about the most appropriate treatment options. Your doctor or specialist may have experience treating these specific populations.

Technivie is a new medication and some things are unknown about its effect in people. Make sure your doctor knows about all of your medical conditions when you are discussing Technivie as a treatment option.

Side effects

The most common side effects of Technivie are:

- lack of energy (fatigue)
- headache
- weakness

In most cases, these side effects are mild or moderate and temporary.

Drug interactions

Always consult your doctor and pharmacist about all of the prescription and non-prescription drugs you are taking, including methadone or other opiate substitution therapies, herbs, supplements and street drugs.

Drug interactions occur when one medication affects how another is absorbed, used or flushed out of the body. Some drugs can interact with the drugs in Technivie, increasing or decreasing the level of one or both drugs in the body. Increased levels can lead to new or more severe side effects. Decreased levels may mean that the drug won't be as effective.

The following medications should **not** be taken with Technivie. This is not a complete list of medications that should not be taken with Technivie:

- medicine to treat irregular heartbeat, such as flecainide, propafenone and quinidine
- medicine to treat the symptoms of an enlarged prostate gland, such as alfuzosin (Xatral)
- medicine to prevent seizures, such as carbamazepine (Tegretol), phenytoin (Dilantin) and phenobarbital
- HIV medicines, such as etravirine (Intelence), nevirapine (Viramune), rilpivirine (Edurant, Complera), those that contain efavirenz (Sustiva, Atripla) and those that contain ritonavir (Norvir), such as Kaletra (lopinavir/ritonavir)
- pain medicine, such as alfentanil or fentanyl (Abstral, Duragesic)
- medicine to treat migraines that contain ergot, such as dihydroergotamine (Migranal) and ergotamine (Bellergal Spacetabs)
- medicine to lower cholesterol, such as atorvastatin, lovastatin and simvastatin
- medicine to treat sleep problems and/or anxiety, such as midazolam (when taken by mouth) and triazolam
- medicine to treat sleep problems, such as modafinil (Alertec) and triazolam
- medicine to treat gout, a form of arthritis, such as colchicine
- medicine to treat schizophrenia, such as quetiapine
- medicine to control verbal or motor tics, such as pimozide (Orap)
- tuberculosis medicine, such as rifampin (Rofact)
- medicine used to treat asthma, such as salmeterol (Advair Diskus, Serevent Diskus)
- medicine to treat allergies, such as astemizole and terfenadine
- medicine for the lung problem pulmonary hypertension, such as sildenafil (Revatio) and bosentan (Tracleer)
- contraceptive pills or vaginal rings that contain ethinyl estradiol, which is a very common form of contraception

- medicine to lower immune response or prevent organ transplant failure, such as sirolimus (Rapamune)
- any medicinal herbs, especially an herb used to treat depression – St. John’s wort (*Hypericum perforatum*), or hyperforin and hypericin, active ingredients in St. John’s wort

When Technivie is taken with the following medications it could potentially cause drug interactions. This is not a complete list of possible drug interactions with the medications in Technivie:

- asthma medication, such as fluticasone (Advair, Flonase, Flovent Diskus, Flovent HFA)
- some HIV medications, such as atazanavir (Reyataz) and darunavir (Prezista and in Prezcoibix)
- medicine to treat indigestion, heartburn or ulcers, such as omeprazole (Losec)
- medicine to treat fungal infection, such as ketoconazole, itraconazole, posaconazole and voriconazole
- medicine to treat anxiety, such as alprazolam (Xanax)
- medicine to treat opioid overdose, such as naloxone
- medicine to treat opioid substance use, such as buprenorphine
- medicine to treat irregular heartbeat, such as amiodarone and digoxin (Toloxin)
- medicine to treat heart disease, such as fluvastatin (Lescol)
- medicine to reduce swelling and fluid retention, such as furosemide
- medicine to treat high blood pressure, such as candesartan, losartan and valsartan, and calcium channel blockers, such as amlodipine (Norvasc)
- medicine to treat pain in the heart caused by decreased blood flow (angina), such as diltiazem, nifedipine and verapamil

- medicine to lower cholesterol, such as rosuvastatin (Crestor), atorvastatin (Lipitor) and pravastatin (Pravachol)
- medicine to lower immune response or prevent organ transplant failure, such cyclosporine (Neoral, Sandimmune) and tacrolimus (Prograf)
- medicine to prevent blood clots, such as warfarin (Coumadin)

Talk to your nurse, doctor and pharmacist if you are taking any of these medicines. One way to manage drug interactions is to make sure that your doctor and pharmacist know about *everything* you are taking, including prescription drugs, over-the-counter drugs, street drugs, herbal medications, supplements or anything else. If you have more than one doctor or pharmacist, it is possible for drug interactions to get missed. If more than one doctor is writing prescriptions for you, let each one know about everything you are taking. If possible, use the same pharmacy for all your prescriptions.

Drug resistance

Drug resistance develops when a virus mutates, or changes, during the replication process. Some mutations of the virus may be able to resist hepatitis C medications. When this happens, the medication becomes less effective or stops working. Resistance can develop when a person does not take their medication as prescribed and directed.

In clinical trials, it was rare for the hepatitis C virus to develop resistance to the drugs in Technivie. However, it is still important for people taking Technivie to take it exactly as prescribed. If you skip or miss doses, the level of drugs inside Technivie can potentially fall to low levels in your body. This can allow the hepatitis C virus to mutate and become able to resist the effect of treatment.

Availability

Technivie, manufactured by AbbVie, has been approved by Health Canada and is available in Canada.

Your nurse, doctor or pharmacist can tell you more about availability and coverage of Technivie in your region.

CATIE's online Treatment coverage in your region section of *Hepatitis C: An in-depth guide* on www.catie.ca contains information about provincial and territorial drug coverage.

Acknowledgement

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References

AbbVie Corporation. Technivie. *Product monograph*. 2015.

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Disclaimer

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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