

## Technivie™ (Ombitasvir/Paritaprevir/Ritonavir) & Ribavirin Treatment Agreement

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**Family Medicine Provider:** \_\_\_\_\_

If you are considering hepatitis C treatment, please read this treatment agreement carefully and be sure to ask any questions you may have before you sign the form.

In 2015 the FDA approved ombitasvir, paritaprevir, & ritonavir tablets (Technivie™) to be given for 12 weeks with ribavirin for the treatment of hepatitis C genotype 4 without cirrhosis. Treatment with Technivie™ and ribavirin requires 6 scheduled visits over 6 months.

### **PREGNANCY & BREASTFEEDING WARNING**

It is not known if Technivie™ will harm an unborn or breastfeeding baby. However, ribavirin can harm an unborn child or breastfeeding infant. A woman must not get pregnant and a man must not father a child while taking ribavirin or for 6 months after treatment. You must **use 2 forms of birth control** when you take ribavirin and for 6 months after your last dose.

You must stop using ethinyl estradiol-containing medicines before you start treatment with Technivie™. 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 finishing treatment with Technivie™.

#### **Acceptable Birth Control Methods (must use 2):**

- Progestin only contraceptives (e.g. mini pill, Depo shot, Nexplanon®)
- Male or female condom
- Spermicides (creams, films, foams, gels, and/or suppositories)
- Diaphragm or cervical cap
- Intrauterine device (IUD), Today® vaginal sponge

#### **Unacceptable Birth Control Methods:**

- Rhythm method or withdrawal

## **HOW THE TREATMENT PROCESS WORKS**

You will have blood and urine tests.

- These tests will include a pregnancy test for female patients of childbearing age. Urine pregnancy tests will be done monthly during clinic visits. If you are a woman and your treatment includes ribavirin it is recommended that you continue monthly home pregnancy testing for 6 months after treatment and notify your healthcare provider if you become pregnant. Female partners of males whose treatment includes ribavirin should do a monthly home pregnancy test during treatment and for 6 months after treatment completion and notify their health care provider if they become pregnant.
- Random drug and alcohol tests may be requested.
- At each visit, about 2-3 tubes of blood will be collected. Other examinations and tests may be done during the treatment if your provider feels there is a need.

Your first three visits will be at the start of treatment (week 0) and weeks 2 and 4 after you begin taking the medications. After that, the visits will be once each month until you stop taking the medications.

**You may need to come to the clinic or see your primary care provider more frequently if you are having side effects or problems related to the treatment.**

You will have a liver clinic visit 3 months after treatment completion and then yearly (corresponding to your end of treatment date) for 5 years. If you have cirrhosis you should continue to have a liver ultrasound and alpha fetoprotein (AFP) cancer screening blood test every six months and regular clinic visits.

## **TREATMENT MEDICATIONS AND SIDE EFFECTS**

Technivie™ is ombitasvir, paritaprevir, and ritonavir in a fixed-dose combination tablet packaged for oral use. It is two pink oblong tablets containing ombitasvir 12.5mg, paritaprevir 75mg, and ritonavir 50mg taken at the same time daily (in the morning) with a meal. Store the medication at room temperature.

If you miss a dose, 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. Take your next dose at your regular time with a meal. If you miss a dose and it is more than 12 hours from the time you usually take your dose, do not take the missed dose. Take your next dose at your regular time with a meal.

**Do not take more than the prescribed dose of Technivie™ to make up for a missed dose. Do not take Technivie™ if you have had a severe skin rash after taking ritonavir (Norvir®).**

Tell your healthcare provider if you are taking any of the following medicines; as they are contraindicated with Technivie™:

- Alfuzosin hydrochloride (Uroxatral®)
- Colchicine (COLCRYS, Mitigare®)
- Carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®); Phenytoin (Dilantin®, Phenytek®); Phenobarbital (Luminal®); Primidone (Mysoline®)
- Efavirenz (Atripla®, Sustiva®)
- Ergot containing medicines including: ergotamine tartrate (Cafergot®, Ergomar®, Ergostat®, Medihaler®); dihydroergotamine mesylate (D.H.E. 45®, Migranal®); methylergonovine (Methergine®); ergonovine (Ergotrate®)
- Ethinyl estradiol-containing medications; combination birth control pills or patches, such as Lo Loestrin® FE, Norinyl®, Ortho Tri-Cyclen Lo®, Ortho Evra®; hormonal vaginal rings such as NuvaRing®; hormonal replacement therapy medicine Fem HRT®.
- Lovastatin (Advicor®, Altoprev®, Mevacor®); Simvastatin (Simcor®, Vytorin®, Zocor®)
- Midazolam, when taken by mouth; Triazolam (Halcion®)
- Pimozide (Orap®)
- Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- Sildenafil citrate (Revatio®) when taken for pulmonary artery hypertension
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort

Tell your healthcare provider if you are taking any of the following medicines; as they are not recommended with Technivie™:

- Atazanavir (Reyataz®) or atazanavir (Reyataz®)/ ritonavir; lopinavir/ ritonavir (Kaletra®), rilpivirine (Edurant®, Complera®, Odefsey®)

Tell your healthcare provider if you are taking any of the following medicines; as dosage adjustments or monitoring may be recommended:

- Amiodarone (Cordarone<sup>®</sup>, Nexterone<sup>®</sup>, Pacerone<sup>®</sup>); bepridil; disopyramide (Norpace<sup>®</sup>, Norpace CR<sup>®</sup>); flecainide (Tambocor<sup>™</sup>); systemic lidocaine (Xylocaine<sup>®</sup>); mexiletine; propafenone (Rythmol, Rythmol SR); quinidine (Nuedexta<sup>®</sup>)
- Digoxin (Lanoxicaps<sup>®</sup>, Lanoxin<sup>®</sup>)
- Amlodipine (Norvasc<sup>®</sup>)
- Furosemide (Lasix<sup>®</sup>)
- Ketoconazole; Voriconazole (Vfend<sup>®</sup>)
- Fluticasone (Inhaled- Arnuity<sup>™</sup> Ellipta<sup>®</sup>, Breo Ellipta<sup>®</sup>, Flovent<sup>®</sup>, Advair<sup>®</sup>; Nasal – Flonase<sup>®</sup>, Veramyst, Dymista<sup>®</sup>); Salmeterol (Serevent, Advair<sup>®</sup>)
- Darunavir (Prezista<sup>®</sup>) / Ritonavir
- Pravastatin (Pravachol<sup>®</sup>)
- Cyclosporine (Gengraf<sup>®</sup>, Neoral<sup>®</sup>, Sandimmune<sup>®</sup>)
- Buprenorphine/naloxone (Suboxone<sup>®</sup>)
- Omeprazole (Prilosec<sup>®</sup>, Prilosec OTC<sup>®</sup>)
- Alprazolam (Xanax<sup>®</sup>)
- Quetiapine (Seroquel<sup>®</sup>)

**Ribavirin** is a 200mg capsule or tablet. You will take ribavirin pills twice daily by mouth with food (dose is based on your weight, except for those who have had a liver transplant). Ribavirin dose may be adjusted based on your tolerance of this medication. You should not miss/skip taking any pills. A common side effect is anemia. Anemia is a condition where the blood has a decreased number of red blood cells. This occurs more often in older persons taking ribavirin. Anemia can be serious in patients who have kidney problems. In patients who have coronary artery disease (narrowing of the blood vessels in the heart), anemia may make the problem worse, leading to chest pain or heart attack. If your provider believes you may have coronary artery disease, you will be tested for this and excluded from treatment if it is serious.

- Other common side effects include: headache, trouble sleeping, nausea, vomiting, weakness or lack of energy, shortness of breath, loss of appetite, itching, cough, muscle pain, swelling and pain in your joints (gout), depression, nervousness, and dizziness.
- Studies in animals have shown when ribavirin is given to pregnant females, death of the developing embryo or birth of deformed baby animals may result. It is expected that similar results as seen in the animal studies could occur in humans.

The most common side effects of Technivie™ given with ribavirin are tiredness, nausea, sleep problems, and feeling weak.

**PLEASE NOTE:**

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Technivie™ & ribavirin prior to starting any new medications. You must let Liver Clinic providers know about any new medications you are prescribed before starting them. This includes vitamins and other supplements.

\*\*\* Hepatitis C treatment should not cause pain that requires narcotic pain medication.

**BENEFITS OF TREATMENT**

In most cases, hepatitis C will respond to treatment as determined by a blood test that measures the presence and amount of hepatitis C in the blood. If you have no hepatitis C in your blood 12 weeks **after** the end of treatment, this is called a “sustained virologic response” and means you no longer have hepatitis C. Your chance of achieving a sustained virologic response depends on the hepatitis C genotype, how much hepatitis C virus you have in your blood at the beginning of treatment, any past treatment response, and how much liver damage you have had prior to treatment.

It is possible that you may develop some serious side effects, which will require you to stop the treatment. You may still benefit from treatment even if it does not get rid of your hepatitis C, as it may slow down the disease. You may choose to stop treatment at any time.

**In Clinical Trials:**

Persons with genotype 4 who did not have cirrhosis were treated with Technivie™ and ribavirin for 12 weeks and had a 100% response (cure) rate (42 of 42 persons treated).

**WHOM TO CALL**

If you have any questions about your treatment, contact the Liver Disease & Hepatitis Program @ 907-729-1560 or your primary care provider.

**TREATMENT AGREEMENT**

**To receive treatment, please review the following statements and initial beside the responses:**

\_\_\_\_\_ I agree not to drink alcohol or use recreational drugs during the treatment.

\_\_\_\_\_ I will tell my provider if I have any serious medical conditions (such as heart disease, high blood pressure, diabetes, high cholesterol, rheumatoid arthritis, or drug addiction), or psychiatric conditions (depression, history of suicide attempts, bipolar disorder, or psychosis).

\_\_\_\_\_ I am willing to visit the clinic and see a provider on a regular schedule for the entire length of the treatment. If I am unable to attend an appointment, I will let my provider know this ahead of time and I will reschedule my appointment.

\_\_\_\_\_ I understand that my treatment will be stopped if I cannot attend appointments as required to evaluate my health and well-being during treatment and the effectiveness of treatment.

\_\_\_\_\_ I will use 2 acceptable methods of birth control during treatment and for 6 months after I stop treatment (see lists, page 1).

\_\_\_\_\_ As a female, I understand that I cannot be pregnant or breastfeeding during the treatment and for 6 months after treatment. I understand that my treatment will be stopped if I become pregnant. \_\_\_\_\_ Not applicable, I am surgically sterile or post-menopausal.

\_\_\_\_\_ As a male taking ribavirin I understand that I should not father a child during treatment and for 6 months after treatment.

\_\_\_\_\_ If I have any problems with the medications or side effects that bother me, I will let my provider or nurse know right away.

\_\_\_\_\_ I understand that my hepatitis C may not respond to treatment.

\_\_\_\_\_ I understand that my provider can stop my treatment if the provider feels that stopping it is in the best interest of my health and welfare.

\_\_\_\_\_ I will do my best to take my medications as prescribed by my provider. If I am unable to do so, I will contact my provider.

\_\_\_\_\_ I will protect myself and others from hepatitis C by not sharing needles, toothbrushes, razors or nail clippers and covering cuts to prevent blood exposure.

**My signature below means that I have read this treatment agreement and/or the meaning of the information has been explained to me. I agree to treatment.**

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<b>Patient's Name (PLEASE PRINT)</b>	<b>Patient's Signature</b>	<b>Date</b>
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<b>Provider's Name (PLEASE PRINT)</b>	<b>Provider's Signature</b>	<b>Date</b>
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