MEDICATION GUIDE
VIEKIRA PAK (vee-KEE-rah-pak)
(ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
co-packaged for oral use

Important: When taking VIEKIRA PAK 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 VIEKIRA PAK?
VIEKIRA PAK can cause serious side effects, including:

- **Hepatitis B virus reactivation**: Before starting treatment with VIEKIRA PAK, 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 VIEKIRA PAK. 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 VIEKIRA PAK.
- **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 VIEKIRA PAK.
- **Increase 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 VIEKIRA PAK. See the section **"Do not take VIEKIRA PAK 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 VIEKIRA PAK, and for about **2** weeks after you finish treatment with VIEKIRA PAK. 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 VIEKIRA PAK.
  - Your healthcare provider may tell you to stop taking VIEKIRA PAK 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 VIEKIRA PAK:

- 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

For more information about side effects, see the section "What are the possible side effects of VIEKIRA PAK?"

What is VIEKIRA PAK?
VIEKIRA PAK is a prescription medicine used with or without ribavirin to treat adults with genotype 1 chronic (lasting a long time) hepatitis C virus (HCV) infection.
VIEKIRA PAK can be used in people who have compensated cirrhosis.

VIEKIRA PAK is not for people with advanced cirrhosis (decompensated). If you have cirrhosis, talk to your healthcare provider before taking VIEKIRA PAK.
VIEKIRA PAK contains 2 different types of tablets:

- The pink tablet contains the medicines ombitasvir, paritaprevir and ritonavir
- The beige tablet contains dasabuvir

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

Do not take VIEKIRA PAK if you:

- have moderate or severe liver problems
- take any of the following medicines:
  - alfuzosin hydrochloride
  - apalutamide
  - 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
    - hormone replacement therapy
  - everolimus
  - gemfibrozil
  - lomitapide
  - lovastatin
  - lurasidone
  - midazolam, when taken by mouth
  - phenytoin
  - phenobarbital
  - pimozide
  - 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 VIEKIRA PAK, 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 VIEKIRA PAK.
  - 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 VIEKIRA PAK or if you have to stop VIEKIRA PAK 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 VIEKIRA PAK will harm your unborn baby. You or your partner must take extreme care not to become pregnant during treatment with VIEKIRA PAK with ribavirin and for 6 months after stopping ribavirin. Tell your healthcare provider right away if you or your partner become pregnant. **When taking VIEKIRA PAK 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 VIEKIRA PAK passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take VIEKIRA PAK.

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 VIEKIRA PAK.

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 VIEKIRA PAK.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take VIEKIRA PAK with other medicines.
- If your healthcare provider changed the dose of one of your usual medicines during treatment with VIEKIRA PAK, ask your healthcare provider about when you should change back to your original dose after you finish treatment with VIEKIRA PAK.
- If your healthcare provider told you to stop taking one of your usual medicines during treatment with VIEKIRA PAK, ask your healthcare provider if you should start taking these medicines again after you finish treatment with VIEKIRA PAK.

How should I take VIEKIRA PAK?

- Take VIEKIRA PAK exactly as your healthcare provider tells you to take it. Do not change your dose.
- Do not stop taking VIEKIRA PAK without first talking with your healthcare provider.
- Take VIEKIRA PAK tablets every day, with a meal.
- VIEKIRA PAK comes in **monthly cartons that contain enough medicine for 28 days**.
  - Each monthly carton of VIEKIRA PAK 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 VIEKIRA PAK medicine for **1 day** (4 tablets). Follow the instructions on each child resistant daily dose pack about how to remove the

tablets.

- Take VIEKIRA PAK tablets with a meal as follows:
  - Take the **2** pink tablets (ombitasvir, paritaprevir, and ritonavir), with **1** of the beige tablets (dasabuvir), at about the same time every morning.
  - Take the **second** beige tablet (dasabuvir), at about the same time every evening.
- It is important that you do not miss or skip doses of VIEKIRA PAK during treatment.
- If you take too much VIEKIRA PAK, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of VIEKIRA PAK?
VIEKIRA PAK can cause serious side effects, including:
See "What is the most important information I should know about VIEKIRA PAK?"
Common side effects of VIEKIRA PAK when used with ribavirin include:

- tiredness
- nausea
- itching
- skin reactions such as redness or rash
- sleep problems
- feeling weak

Common side effects of VIEKIRA PAK when used without ribavirin include:

- nausea
- itching
- sleep problems

These are not all the possible side effects of VIEKIRA PAK. 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 VIEKIRA PAK?
Store VIEKIRA PAK at or below 86°F (30°C). Do not remove tablets from the daily dose pack until you are ready to take them.
Keep VIEKIRA PAK and all medicines out of the reach of children.

General information about the safe and effective use of VIEKIRA PAK
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIEKIRA PAK for a condition for which it was not prescribed. Do not give VIEKIRA PAK 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 VIEKIRA PAK that is written for health professionals.

What are the ingredients in VIEKIRA PAK?
Ombitasvir, paritaprevir, and ritonavir tablets:
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.
Dasabuvir tablets:
Active ingredients: dasabuvir
Inactive ingredients: microcrystalline cellulose (D50-100 um), microcrystalline cellulose (D50-50 um), lactose monohydrate, copovidone, croscarmellose sodium, colloidal silicon dioxide/anhydrous colloidal silica, magnesium stearate, polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350/macrogol 3350, talc and iron oxide yellow, iron oxide red and iron

oxide black.

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

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For more information, go to www.viekira.com or call 1-844-484-3547.

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

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