

**MEDICATION GUIDE**  
**VIEKIRA XR (vee-KEE-rah-XR)**  
**(dasabuvir, ombitasvir, paritaprevir, and ritonavir) extended-release tablets**  
**for oral use**

**Important: When taking VIEKIRA XR 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 XR?**

VIEKIRA XR can cause serious side effects, including,

**Hepatitis B virus reactivation:** Before starting treatment with VIEKIRA XR, 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 of hepatitis C virus with VIEKIRA XR. Hepatitis B virus becoming 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 XR.

VIEKIRA XR 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.

VIEKIRA XR 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 VIEKIRA XR. See the section **“Who should not take VIEKIRA XR?”** 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 XR, and for about **2** weeks after you finish treatment with VIEKIRA XR. 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 XR.
- Your healthcare provider may tell you to stop taking VIEKIRA XR 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 XR:
  - 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 XR?”**

**What is VIEKIRA XR?**

- VIEKIRA XR is a prescription medicine used with or without ribavirin to treat people with genotype 1 chronic (lasting a long time) hepatitis C virus (HCV) infection.
- VIEKIRA XR can be used in people who have compensated cirrhosis.
- VIEKIRA XR is not for people with advanced cirrhosis (decompensated). If you have cirrhosis, talk to your healthcare provider before taking VIEKIRA XR. VIEKIRA XR is not for people with certain types of liver problems.

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

**Who should not take VIEKIRA XR?**

**Do not take VIEKIRA XR if you:**

- **have certain liver problems**
- **take any of the following medicines:**
  - alfuzosin hydrochloride (Uroxatral<sup>®</sup>)
  - atorvastatin (Caduet<sup>®</sup>, Lipitor<sup>®</sup>, Liptruzet<sup>®</sup>)
  - carbamazepine (Carbatrol<sup>®</sup>, Eptitol<sup>®</sup>, Equetro<sup>®</sup>, Tegretol<sup>®</sup>, TEGRETOL-XR<sup>®</sup>, TERIL<sup>®</sup>)
  - cisapride (Propulsid<sup>®</sup>)

- colchicine (Colcrys<sup>®</sup>) in patients who have certain kidney or liver problems
- dronedarone (Multaq<sup>®</sup>)
- efavirenz (Atripla<sup>®</sup>, Sustiva<sup>®</sup>)
- ergot containing medicines including:
  - ergotamine tartrate (Cafergot<sup>®</sup>, Ergomar<sup>®</sup>, Ergostat<sup>®</sup>, Medihaler<sup>®</sup>, Migergot<sup>®</sup>, Wigraine<sup>®</sup>, Wigrettes<sup>®</sup>)
  - dihydroergotamine mesylate (D.H.E. 45<sup>®</sup>, Migranal<sup>®</sup>)
  - methylergonovine (Ergorate<sup>®</sup>, Methergine<sup>®</sup>)
- ethinyl estradiol-containing medicines:
  - combination birth control pills or patches, such as Lo Loestrin<sup>®</sup> FE, Norinyl<sup>®</sup>, Ortho Tri-Cyclen Lo<sup>®</sup>, Ortho Evra<sup>®</sup>
  - hormonal vaginal rings such as NuvaRing<sup>®</sup>
  - the hormone replacement therapy medicine, Fem HRT<sup>®</sup>
- everolimus (Afinitor<sup>®</sup>, Zortress<sup>®</sup>)
- gemfibrozil (Lopid<sup>®</sup>)
- lovastatin (Advicor<sup>®</sup>, Altoprev<sup>®</sup>, Mevacor<sup>®</sup>)
- lurasidone (Latuda<sup>®</sup>)
- midazolam, when taken by mouth
- phenytoin (Dilantin<sup>®</sup>, Phenytek<sup>®</sup>)
- phenobarbital (Luminal<sup>®</sup>)
- pimozide (Orap<sup>®</sup>)
- ranolazine (Ranexa<sup>®</sup>)
- rifampin (Rifadin<sup>®</sup>, Rifamate<sup>®</sup>, Rifater<sup>®</sup>, Rimactane)
- sildenafil citrate (Revatio<sup>®</sup>), when taking for pulmonary artery hypertension (PAH)
- simvastatin (Simcor<sup>®</sup>, Vytorin<sup>®</sup>, Zocor<sup>®</sup>)
- sirolimus (Rapamune<sup>®</sup>)
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
- tacrolimus (Astagraf XL<sup>®</sup>, Envarsus XR<sup>®</sup>, Prograf<sup>®</sup>)
- Triazolam (Halcion<sup>®</sup>)
- **have had a severe skin rash after taking ritonavir (Norvir<sup>®</sup>)**

**What should I tell my healthcare provider before taking VIEKIRA XR?**

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

- have ever had hepatitis B virus infection
- have liver problems other than hepatitis C infection. **See “Who should not take VIEKIRA XR?”**
- have HIV infection
- have had a liver transplant. If you take cyclosporine (Gengraf<sup>®</sup>, Neoral<sup>®</sup>, Sandimmune<sup>®</sup>) to help prevent rejection of your transplanted liver, the amount of this medicine in your blood may increase during treatment with VIEKIRA XR.
  - 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 XR or if you have to stop VIEKIRA XR 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 XR will harm your unborn baby. **When taking VIEKIRA XR 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 XR passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take VIEKIRA XR.

**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 XR. **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 XR.
- **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 XR with other medicines.

- When you finish treatment with VIEKIRA XR:
  - If your healthcare provider changed the dose of one of your usual medicines during treatment with VIEKIRA XR: Ask your healthcare provider about when you should change back to your original dose after you finish treatment with VIEKIRA XR.
  - If your healthcare provider told you to stop taking one of your usual medicines during treatment with VIEKIRA XR: Ask your healthcare provider if you should start taking these medicines again after you finished treatment with VIEKIRA XR.

#### **How should I take VIEKIRA XR?**

- Take VIEKIRA XR exactly as your healthcare provider tells you to take it. Do not change your dose.
- Do not stop taking VIEKIRA XR without first talking with your healthcare provider.
- Take VIEKIRA XR tablets one time each day.
- **VIEKIRA XR tablets must be taken with a meal.**
- Swallow VIEKIRA XR tablets whole. Do not split, crush, or chew the tablets.
- Do not drink alcohol within 4 hours of taking VIEKIRA XR.
- VIEKIRA XR comes in **monthly cartons that contain enough medicine for 28 days.**
  - Each monthly carton of VIEKIRA XR 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 VIEKIRA XR medicine for **1 day** (3 tablets). Follow the instructions on each daily dose pack about how to remove the tablets.
- It is important that you do not miss or skip doses of VIEKIRA XR during treatment.
- If you take too much VIEKIRA XR, call your healthcare provider or go to the nearest hospital emergency room right away.

#### **What are the possible side effects of VIEKIRA XR?**

##### **VIEKIRA XR can cause serious side effects, including:**

- Hepatitis B virus reactivation. See “What is the most important information I should know about VIEKIRA XR?”

Common side effects of VIEKIRA XR when used with ribavirin include:

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

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

- nausea
- itching
- sleep problems

These are not all the possible side effects of VIEKIRA XR. 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 XR?**

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

**Keep VIEKIRA XR and all medicines out of the reach of children.**

#### **General information about the safe and effective use of VIEKIRA XR**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VIEKIRA XR for a condition for which it was not prescribed. Do not give VIEKIRA XR 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 XR that is written for health professionals.

#### **What are the ingredients in VIEKIRA XR?**

**Active ingredients:** dasabuvir, ombitasvir, paritaprevir, and ritonavir

##### **Inactive ingredients:**

- The extended release layer contains: copovidone, K value 28, hypromellose 2208, 17,700 (mPa\*s), colloidal silicon dioxide/colloidal anhydrous silica, and magnesium stearate.
- The immediate release layer contains: copovidone, K value 28, vitamin E polyethylene glycol succinate, propylene glycol monolaurate, sorbitan monolaurate, colloidal silicon dioxide/colloidal anhydrous silica.
- The tablet coating contains: hypromellose (6 mPa\*s), hypromellose (15 mPa\*s), polyethylene glycol

400, hydroxypropyl cellulose, polysorbate 80, polyethylene glycol 3350/macrogol 4000, talc, titanium dioxide, colloidal silicon dioxide/colloidal anhydrous silica and iron oxide yellow.

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For more information go to [www.viekira.com](http://www.viekira.com) or call 1-844-843-5472.

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