

Important Update to the Medication Guide for VIEKIRA PAK® (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) and VIEKIRA XR™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir) extended-release tablets

In February 2017 and March 2017, the VIEKIRA PAK/VIEKIRA XR (VIEKIRA) Medication Guides were updated and key highlights are listed below. These highlights are not all-inclusive of the changes to the VIEKIRA Medication Guides. Please refer to the complete Medication Guide to review additional changes.

What is the most important information I should know about VIEKIRA?

This section was updated to include important information about the risk of Hepatitis B virus reactivation, and now reads as follows:

Hepatitis B virus (HBV) reactivation: Before starting treatment with VIEKIRA, 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. 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.

Who should not take VIEKIRA?

This section was updated to include additional medicines that are not to be taken with VIEKIRA.

Do not take VIEKIRA if you take any of the following medicines:

- atorvastatin (Caduet®, Lipitor®, Liptruzet®)
- everolimus (Afinitor®, Zortress®)
- sirolimus (Rapamune®)
- tacrolimus (Astagraf XL®, Envarsus XR®, Prograf®)

This is not the complete safety information for VIEKIRA, for additional information please see below.

Please see VIEKIRA XR full [Prescribing Information](#), including the [Medication Guide](#).

Please see VIEKIRA PAK full [Prescribing Information](#), including the [Medication Guide](#).

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VIEKIRA XR™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir) extended-release tablets / VIEKIRA PAK® (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) (VIEKIRA) are prescription medicines used with or without ribavirin to treat adults with genotype 1 chronic (lasting a long time) hepatitis C (hep C) virus infection.

VIEKIRA can be used in people who have compensated cirrhosis.

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

IMPORTANT SAFETY INFORMATION

When taking VIEKIRA in combination with ribavirin, you should read the Medication Guide that comes with ribavirin, especially the important pregnancy information.

What is the most important information I should know about VIEKIRA?

VIEKIRA can cause serious side effects, including:

- **Hepatitis B virus reactivation:** Before starting treatment with VIEKIRA, your doctor 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. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure and death. Your doctor will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking VIEKIRA.
- VIEKIRA 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 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 (combination birth control pills or patches, such as Lo Loestrin[®] FE, Norinyl[®], Ortho Tri-Cyclen Lo[®], Ortho Evra[®]; hormonal vaginal rings such as NuvaRing[®]; and the hormone replacement therapy medicine, Fem HRT[®]) before you start treatment with VIEKIRA. If you use these medicines as a method of birth control, you must use another method during treatment with VIEKIRA, and for about 2 weeks after you finish treatment with VIEKIRA. Your doctor will tell you when you may begin taking ethinyl estradiol-containing medicines.
- Your doctor should do blood tests to check your liver function during the first 4 weeks of treatment and then as needed.
- Your doctor may tell you to stop taking VIEKIRA if you develop signs or symptoms of liver problems. Tell your doctor right away if you develop any of the following symptoms, or if they worsen during treatment with VIEKIRA: tiredness, weakness, loss of appetite, nausea, vomiting, yellowing of the skin or eyes, color changes in stools, confusion, or swelling of the stomach area.

Do not take VIEKIRA if you:

- **have certain liver problems**
- **take any of the following medicines:** alfuzosin hydrochloride (Uroxatral[®]) • atorvastatin (Caduet[®], Lipitor[®], Liptruzet[™]) • carbamazepine (Carbatrol[®], Epitol[®], Equetro[®], Tegretol[®], TEGRETOL[®]-XR, TERIL[®]) • cisapride (Propulsid[®]) • colchicine (Colcrys[®]), in patients who have certain kidney or liver problems • dronedarone (Multaq[®]) • efavirenz (Atripla[®], Sustiva[®]) • ergot-containing medicines, including ergotamine tartrate (Cafergot[®], Ergomar[®], Ergostat[®], Medihaler[®], Migergot[®], Wigraine[®], Wigrettes[®]), dihydroergotamine mesylate (D.H.E. 45[®], Migranal[®]), methylergonovine (Ergotrate[®], Methergine[®]) • ethinyl estradiol-containing medicines • everolimus (Afinitor[®], Zortress[®]) • gemfibrozil (Lopid[®]) • lovastatin (Advicor[®], Altoprev[®], Mevacor[®]) • lurasidone (Latuda[®]) • midazolam (when taken by mouth) • phenytoin (Dilantin[®], Phenytek[®]) • phenobarbital (Luminal[®]) • pimozone (Orap[®]) • ranolazine (Ranexa[®]) • rifampin (Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®]) • sildenafil citrate (Revatio[®]), when taken for pulmonary artery hypertension (PAH) • simvastatin (Simcor[®], Vytorin[®], Zocor[®]) • sirolimus (Rapamune[®]) • St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort • tacrolimus (Astagraf XL[®], Envarsus XR[®], Prograf[®]) • triazolam (Halcion[®])
- **have had a severe skin rash after taking ritonavir (Norvir[®])**

What should I tell my doctor before taking VIEKIRA?

- If you have ever had hepatitis B virus infection, liver problems other than hep C infection, HIV infection, or any other medical conditions.
- If you have had a liver transplant. If you take the medicine cyclosporine (Gengraf[®], Neoral[®], Sandimmune[®]), your doctor should check your blood levels and, if needed, may change your dose of this medicine or how often you take it, both during and after treatment with VIEKIRA.

- If you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed. It is not known if VIEKIRA will harm your unborn baby or pass into your breast milk. Talk to your doctor about the best way to feed your baby if you take VIEKIRA.
- **About all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with VIEKIRA.
- **Do not start taking a new medicine without telling your doctor.** Your doctor can tell you if it is safe to take VIEKIRA with other medicines.
- When you are finished with VIEKIRA, ask your doctor what to do if you had a change in dose or stopped one of your usual medicines during VIEKIRA treatment.

What are the common side effects of VIEKIRA?

- **For VIEKIRA used with ribavirin**, side effects include tiredness, nausea, itching, skin reactions such as redness or rash, sleep problems, and feeling weak.
- **For VIEKIRA used without ribavirin**, side effects include nausea, itching, and sleep problems.

These are not all of the possible side effects of VIEKIRA. Tell your doctor if you have any side effect that bothers you or that does not go away.

This is the most important information to know about VIEKIRA. For more information, talk to your doctor or healthcare provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see VIEKIRA XR full [Prescribing Information](#), including the [Medication Guide](#).

Please see VIEKIRA PAK full [Prescribing Information](#), including the [Medication Guide](#).

If you cannot afford your medication, contact www.pparx.org for assistance.