



Viekira Pak

(ombitasvir, paritaprevir, ritonavir, dasabuvir)

WHAT IS VIEKIRA PAK?

VIEKIRA PAK includes ombitasvir, a hepatitis C virus (HCV) NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir (see fact sheet 442), a CYP3A inhibitor and dasabuvir, a HCV non-nucleoside NS5B polymerase inhibitor. See the HCV life cycle shown in Fact Sheet 670. These drugs makes it harder for the virus to multiply.

Viekira pak is manufactured by Abbvie.

In clinical studies, about 95% of people without cirrhosis taking Viekira Pak had HCV sustained viral response (SVR), meaning that their HCV infection was cured. In clinical studies, between 89 and 99% of people with cirrhosis taking Viekira Pak had SVR.

WHO SHOULD TAKE IT?

Viekira Pak was approved by the FDA in December 2014 as a treatment for adults infected with HCV genotype 1a or 1b. It is not recommended for people with severe (decompensated) liver disease.

Viekira Pak is also not recommended for people who take other medications that are metabolized by specific liver enzymes, called cytochrome P450 (CYP3A and CYP2C8).

The safety and effectiveness of Viekira Pak in patients less than 18 years of age have not been established.

HOW IS IT TAKEN?

Two ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg tablets once daily (in the morning) and one dasabuvir 250 mg tablet twice daily (morning and evening) with a meal without regard to fat or calorie content.

People with HCV genotype 1a or 1b without cirrhosis will take the combination for 12 weeks. People with

genotype 1a or 1b with cirrhosis should take the combination for 24 weeks.

Viekira Pak should be taken with ribavirin (see fact sheet 680) in patients with genotype 1a (with and without cirrhosis) and 1b with cirrhosis. If taken with ribavirin, the warnings and precautions for ribavirin also apply to this combination regimen.

WHAT ARE THE SIDE EFFECTS?

In people taking Viekira Pak with ribavirin, the most commonly reported side effects (greater than 10% of subjects) were fatigue, nausea, itchy skin, other skin reactions, insomnia and weakness.

In people taking Viekira Pak without ribavirin, the most commonly reported side effects (greater than or equal to 5% of subjects) were nausea, itchy skin and insomnia.

These are not the only possible side effects of HCV treatment. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

WHAT ABOUT DRUG RESISTANCE?

Some new copies of HCV carry mutations, meaning they are slightly different from the original virus. Some mutated virus can keep multiplying even when you are taking anti-HCV medications. When this happens, the drug will stop working. This is called "developing resistance" to the drug.

Resistance can develop quickly. It is very important to take antiviral medications according to instructions, on schedule, and not to skip or reduce doses.

HOW DOES IT REACT WITH OTHER DRUGS?

The medications in Viekira Pak can interact with other drugs or supplements that you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose, including the loss of effect of Viekira Pak. The potential for drug interactions must be considered before and during treatment.**

Viekira Pak interacts with some HIV medications and is not recommended for people taking darunavir (see fact sheet 450), lopinavir/ritonavir (see fact sheet 446) or rilpivirine (see fact sheet 435).

Be sure to tell your provider if you take any of the following types of medications: antiarrhythmics, antifungals, calcium channel blockers, inhaled corticosteroids, diuretics, statins, or immunosuppressants.

New drug interactions are being identified all the time. Make sure that your health care provider knows about all the drugs and supplements you are taking.

THE BOTTOM LINE

Viekira Pak is a combination for treating genotype 1a and genotype 1b HCV infection. Viekira Pak cures the majority of people with HCV genotype 1 who took the medication in clinical trials.

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