



ODEFSEY

(rilpivirine + emtricitabine + tenofovir alafenamide)

WHAT IS ODEFSEY?

Odefsey is a tablet that contains three antiretroviral drugs (ARVs) used to fight HIV: rilpivirine (Edurant), emtricitabine (Emtriva), and tenofovir alafenamide (TAF). Odefsey is manufactured by Gilead and Janssen. It is the second single tablet regimen that includes TAF, a new version of tenofovir that has lower bone and kidney risks.

The drugs in Odefsey are a non-nucleoside reverse transcriptase inhibitor (rilpivirine) and two nucleoside analog reverse transcriptase inhibitors, or nukes (emtricitabine and tenofovir). These drugs block the reverse transcriptase enzyme. This enzyme changes HIV's genetic material (RNA) into the form of DNA. This has to occur before HIV's genetic code gets inserted into an infected cell's own genetic codes.

WHO SHOULD TAKE ODEFSEY?

Odefsey was approved in March 2016 as an antiretroviral treatment for people 12 or older with HIV infection who have not already taken antiviral drugs and whose viral load (see fact sheet 125) is below 100,000. Odefsey is also approved as a replacement for stable antiretroviral therapy (ART) in people who have had undetectable viral loads for more than 6 months and never experienced failure of past ART.

While there are no absolute rules about when to start ART, treatment is now recommended for all people living with HIV, independent of your CD4 count. You and your health care provider should consider your viral load, any symptoms you are having, and your attitude about taking ART. Fact Sheet 404 has more information about guidelines for the use of ART.

If you take Odefsey, you can reduce your viral load to extremely low levels, and increase your CD4 cell counts. This should mean staying healthier longer.

Odefsey provides three drugs in one pill. It can be more convenient to use Odefsey than some other combinations of drugs. This could mean fewer missed doses and better control of HIV. Odefsey

can be an effective regimen of ARVs in one pill.

WHO SHOULD NOT TAKE ODEFSEY?

Odefsey should not be used by people who have virus with resistance to the any of the three anti-HIV medications it contains. Odefsey is not recommended for people less than 12 years of age.

Odefsey is a fixed-dose combination. Dosages of the individual components cannot be adjusted. Patients who have severe kidney disease, or severe liver disease, should not use Odefsey.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. They are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called "developing resistance" to the drug. See Fact Sheet 126 for more information on resistance.

Sometimes, if your virus develops resistance to one drug, it will also have resistance to other ARVs. This is called "cross-resistance."

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

HOW IS ODEFSEY TAKEN?

Odefsey is taken by mouth as a tablet. The normal adult dose is one tablet, once a day. Odefsey should be taken with a meal. Each tablet includes 25 milligrams (mg) of rilpivirine, 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide.

Don't change your dose or stop taking Odefsey without talking to your healthcare provider.

WHAT ARE THE SIDE EFFECTS?

When you start any ART, you may have temporary side effects such as

headaches, or a general sense of feeling ill. These side effects usually get better or disappear over time.

Odefsey is usually very well tolerated. The most common side effects of Odefsey are the same as with the drugs it contains: rilpivirine (see fact sheet 435) can cause depression, trouble sleeping and headache. Emtricitabine (see fact sheet 420), and tenofovir (see fact sheet 419) can cause nausea. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

If you have had hepatitis B or C, your liver function tests may increase significantly. Your healthcare provider should monitor your liver health before and during treatment with Odefsey.

HOW DOES ODEFSEY REACT WITH OTHER DRUGS?

Odefsey can interact with other drugs or supplements you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. Make sure that your health care provider knows about ALL drugs and supplements you are taking.**

Drugs to avoid include some antacids. Drugs to watch out for include other ARVs, drugs to treat tuberculosis (see fact sheet 518), for lowering stomach acid (such as omeprazole), erectile dysfunction (such as Viagra), for heart rhythm (antiarrhythmics), and for migraine headaches. Interactions are also possible with several antihistamines (allergy medications), sedatives, drugs to lower cholesterol, and anti-fungal drugs.

The herb **St. John's Wort** (See Fact Sheet 729) lowers the blood levels of some HIV medications. Do not take it with Odefsey.

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