

(oh-DEF-see)

IMPORTANT FACTS

This is only a brief summary of important information about ODEFSEY[®] and does not replace talking to your healthcare provider about your condition and your treatment.

MOST IMPORTANT INFORMATION ABOUT ODEFSEY

ODEFSEY may cause serious side effects, including:

- **Buildup of lactic acid in your blood (lactic acidosis)**, which is a serious medical emergency that can lead to death. Call your healthcare provider right away if you have any of these symptoms: feeling very weak or tired, unusual muscle pain, trouble breathing, stomach pain with nausea or vomiting, feeling cold (especially in your arms and legs), feeling dizzy or lightheaded, and/or a fast or irregular heartbeat.
- **Severe liver problems**, which in some cases can lead to death. Call your healthcare provider right away if you have any of these symptoms: your skin or the white part of your eyes turns yellow (jaundice); dark “tea-colored” urine; loss of appetite; light-colored bowel movements (stools); nausea; and/or pain, aching, or tenderness on the right side of your stomach area.
- **Worsening of hepatitis B (HBV) infection**. ODEFSEY is not approved to treat HBV. If you have both HIV-1 and HBV, your HBV may suddenly get worse if you stop taking ODEFSEY. Do not stop taking ODEFSEY without first talking to your healthcare provider, as they will need to check your health regularly for several months.

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight, or have been taking ODEFSEY or a similar medicine for a long time.

ABOUT ODEFSEY

- ODEFSEY is a prescription medicine used to treat HIV-1 in people 12 years of age and older who have never taken HIV-1 medicines before and who have an amount of HIV-1 in their blood (“viral load”) that is no more than 100,000 copies/mL. ODEFSEY can also be used to replace current HIV-1 medicines for some people who have an undetectable viral load (less than 50 copies/mL), have been on the same HIV-1 medicines for at least 6 months, have never failed HIV-1 treatment, and whose healthcare provider determines that they meet certain other requirements.
- **ODEFSEY does not cure HIV-1 or AIDS**. Ask your healthcare provider about how to prevent passing HIV-1 to others.

Do NOT take ODEFSEY if you:

- Take a medicine that contains: carbamazepine (Carbatrol[®], Epitol[®], Equetro[®], Tegretol[®], Tegretol-XR[®], Teril[®]), dexamethasone (Ozurdex[®], Maxidex[®], Decadron[®], Baycadron[™]), dexlansoprazole (Dexilant[®]), esomeprazole (Nexium[®], Vimovo[®]), lansoprazole (Prevacid[®]), omeprazole (Prilosec[®], Zegerid[®]), oxcarbazepine (Trileptal[®]), pantoprazole sodium (Protonix[®]), phenobarbital (Luminal[®]), phenytoin (Dilantin[®], Dilantin-125[®], Phenytek[®]), rabeprazole (Aciphex[®]), rifampin (Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®]), or rifapentine (Priftin[®]).
- Take the herbal supplement St. John’s wort.
- Take any other HIV-1 medicines at the same time.

POSSIBLE SIDE EFFECTS OF ODEFSEY

ODEFSEY can cause serious side effects, including:

- Those in the “Most Important Information About ODEFSEY” section.
- Severe skin rash and allergic reactions.
- Depression or mood changes.
- Changes in liver enzymes.
- Changes in body fat.
- Changes in your immune system.
- New or worse kidney problems, including kidney failure.
- Bone problems.

The most common side effects of rilpivirine, one of the medicines in ODEFSEY, are depression, trouble sleeping (insomnia), and headache.

The most common side effect of emtricitabine and tenofovir alafenamide, two of the medicines in ODEFSEY, is nausea.

These are not all the possible side effects of ODEFSEY. Tell your healthcare provider right away if you have any new symptoms while taking ODEFSEY.

Your healthcare provider will need to do tests to monitor your health before and during treatment with ODEFSEY.

BEFORE TAKING ODEFSEY

Tell your healthcare provider if you:

- Have or have had any kidney, bone, mental health (depression or suicidal thoughts), or liver problems, including hepatitis infection.
- Have any other medical condition.
- Are pregnant or plan to become pregnant.
- Are breastfeeding (nursing) or plan to breastfeed. Do not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that should not be taken with ODEFSEY.

HOW TO TAKE ODEFSEY

- ODEFSEY is a complete 1-pill, once-a-day HIV-1 medicine.
- Take ODEFSEY with a meal.

GET MORE INFORMATION

- This is only a brief summary of important information about ODEFSEY. Talk to your healthcare provider or pharmacist to learn more.
- Go to ODEFSEY.com or call 1-800-GILEAD-5
- If you need help paying for your medicine, visit ODEFSEY.com for program information.