# Odefsey

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### *WHAT IS ODEFSEY?*

Odefsey is a drug used as part of antiretroviral therapy (ART). Odefsey contains three antiretroviral drugs (ARVs) combined in one tablet:

- emtricitabine (FTC, Emtriva)
- rilpivirine (RPV, Edurant)
- tenofovir alafenamide fumarate (tenofovir AF, TAF, Vemlidy)

The FDA approved Odefsey in 2016 as an ARV for people with HIV infection. Odefsey is manufactured by Gilead Sciences.

Two of the drugs in Odefsey, emtricitabine and tenofovir AF, are nucleoside reverse transcriptase inhibitors (NRTIs). The other drug, rilpivirine, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). NRTIs and NNRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used alone as a complete regimen to treat HIV infection, Odefsey may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Odefsey does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

### *WHO SHOULD TAKE ODEFSEY?*

Odefsey is a three-drug fixed-dose combination medication that is used to treat HIV in adults and children who weigh at least 77 pounds (35 kg):

- who have not received HIV medicines in the past and who have a viral load that is no more than 100,000 copies/mL
  **OR**
- to replace their current HIV medicines when their healthcare provider determines that they meet certain requirements

The safety and effectiveness of Odefsey for treatment of HIV infection has not been established in children who weigh less than 77 pounds (35 kg).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

Odefsey provides three drugs in one pill. It can be more convenient to use Odefsey than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Odefsey must be used in combination with other ARVs for the treatment of HIV infection.**

### *WHO SHOULD NOT TAKE ODEFSEY?*

Do not take Odefsey if you are allergic to emtricitabine, rilpivirine, tenofovir AF, or any of the other ingredients in this drug.

Do not take Odefsey if you are taking any of the following medicines. Taking Odefsey with these medicines may affect how Odefsey works. Odefsey may cause serious or life-threatening side effects or death when used with these medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifampin, rifapentine
- Proton pump inhibitor (PPI) medicines for stomach/intestinal problems: dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, rabeprazole

- Steroid medicine: dexamethasone (more than a single dose)
- Herbal product: St. John's Wort (*Hypericum perforatum*)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with Odefsey.

Odefsey is not recommended in people with severe kidney disease.

### *WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING ODEFSEY?*

Before you take Odefsey, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have liver problems, including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- Have kidney problems
- Have a history of depression or suicidal thoughts

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with Odefsey. It is not known if Odefsey can harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Odefsey. At least one of the medicines in Odefsey (emtricitabine) can pass to your baby in your breastmilk. It is not known if the other medicines in Odefsey can pass into your breast milk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

### *WHAT ABOUT DRUG RESISTANCE?*

Many new copies of HIV are mutations. These new copies 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. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug 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. Each Odefsey tablet contains 200 mg of emtricitabine, 25 mg of rilpivirine, and 25 mg of tenofovir DAF. The recommended dosage of Odefsey for adults and children who weigh at least 77 pounds (35 kg) is one tablet once daily.

Take Odefsey at the same time each day with food. If you are on dialysis, take your daily dose of Odefsey following dialysis.

**You need to take Odefsey in combination with other ARVs.** Your healthcare provider will tell you what medicines to take and how to take them.

### *WHAT ARE THE SIDE EFFECTS?*

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Odefsey are headaches and problems sleeping (insomnia).

Odefsey can cause serious side effects including:

**Worsening of HBV infection.** Your healthcare provider will test you for HBV before starting treatment with Odefsey. If you have HBV infection and take Odefsey, your HBV may get worse (flareup) if you stop taking Odefsey. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not stop taking Odefsey without first talking to your healthcare provider. Do not run out of Odefsey. Refill your prescription or talk to your healthcare provider before your Odefsey is all gone. If you stop taking Odefsey, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking Odefsey.

**Severe skin rash and allergic reactions.** Skin rash is a common side effect of Odefsey. Rash can be serious. Call your healthcare provider right away if you get a rash. In some cases, rash and allergic reactions may need to be treated in a hospital. Stop taking Odefsey and get medical help right away if you develop a rash with any of the following signs or symptoms:

- Fever

- Skin blisters
- Mouth sores
- Redness or swelling of the eyes (conjunctivitis)
- Swelling of the face, lips, mouth, or throat
- Trouble breathing or swallowing
- Pain on the right side of the stomach (abdominal) area
- Dark “tea colored” urine

**Change in liver enzymes.** People with a history of HBV or HCV or who have certain liver enzyme changes may have an increased risk of developing new or worsening liver problems during treatment with Odefsey. Liver problems can also happen during treatment with Odefsey in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with Odefsey.

**Depression or mood changes.** Tell your healthcare provider right away if you have any of the following symptoms:

- Feel sad or hopeless
- Feel anxious or restless
- Have thoughts of hurting yourself (suicide) or have tried to hurt yourself

**New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with Odefsey. Your healthcare provider may tell you to stop taking Odefsey if you develop new or worse kidney problems.

**Too much lactic acid in your blood (lactic acidosis).** Lactic acidosis is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Weakness or being more tired than usual
- Being short of breath or fast breathing
- Cold or blue hands and feet
- Fast or abnormal heartbeat
- Unusual muscle pain
- Stomach pain with nausea and vomiting
- Feel dizzy or lightheaded

**Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms:

- Skin or the white part of your eyes turns yellow
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea or vomiting
- Stomach-area pain

**You may be more likely to get lactic acidosis or serious liver problems if you are assigned female at birth (AFAB) or are very overweight (obese).**

**Immune Reconstitution Inflammatory Syndrome (IRIS).** IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting treatment with Odefsey.

These are not all the possible side effects of Odefsey. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### *HOW DOES ODEFSEY REACT WITH OTHER DRUGS?*

All ARVs 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. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Odefsey with other medicines.

See above for a list of medications that should not be taken with Odefsey.

### *MORE INFORMATION*

Visit the Odefsey website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Apply for the Gilead Advancing Access Program.

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