

**Patient Information**  
**ODEFSEY® (oh-DEF-see)**  
**(emtricitabine, rilpivirine**  
**and tenofovir alafenamide)**  
**tablets**

**Important: Ask your healthcare provider or pharmacist about medicines that should not be taken with ODEFSEY.** For more information, see the section “What should I tell my healthcare provider before taking ODEFSEY?”

Read this Patient Information before you start taking ODEFSEY and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

**What is the most important information I should know about ODEFSEY?**

ODEFSEY can cause serious side effects, including:

- **Worsening of Hepatitis B virus infection.** ODEFSEY is not for use to treat chronic hepatitis B virus (HBV) infection. If you have hepatitis B virus (HBV) infection and take ODEFSEY, your HBV may get worse (flare-up) if you stop taking ODEFSEY. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.
  - Do not run out of ODEFSEY. Refill your prescription or talk to your healthcare provider before your ODEFSEY is all gone.
  - Do not stop taking ODEFSEY without first talking to your healthcare provider.
  - 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.

For more information about side effects, see the section “**What are the possible side effects of ODEFSEY?**”

**What is ODEFSEY?**

ODEFSEY is a prescription medicine that is used to treat Human Immunodeficiency Virus-1 (HIV-1) in people 12 years of age and older:

- who have not received anti-HIV-1 medicines in the past and who have an amount of HIV-1 in their blood (this is called “viral load”) that is no more than 100,000 copies/mL, **or**
- to replace their current anti-HIV-1 medicines:
  - in people who have been on the same anti-HIV-1 medicine regimen for at least 6 months, **and**
  - who have an amount of HIV-1 in their blood that is less than 50 copies/mL, **and**
  - have never failed past HIV-1 treatment.

HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

ODEFSEY contains the prescription medicines emtricitabine, rilpivirine and tenofovir alafenamide.

It is not known if ODEFSEY is safe and effective in children under 12 years of age or who weigh less than 77 lb (35 kg).

**ODEFSEY may help:**

- Reduce the amount of HIV-1 in your blood. This is called “viral load”.
- Increase the number of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

**ODEFSEY does not cure HIV-1 infections or AIDS.** You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

**Avoid doing things that can spread HIV-1 infection to others.**

- Do not share or re-use needles or other injection equipment.

- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
  - Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.
- Ask your healthcare provider if you have any questions about how to prevent passing HIV-1 to other people.

#### **Who should not take ODEFSEY?**

- **Do not take ODEFSEY if you also take a medicine that contains:**
- carbamazepine (CARBATROL<sup>®</sup>, EPITOL<sup>®</sup>, EQUETRO<sup>®</sup>, TEGRETOL<sup>®</sup>, TEGRETOL-XR<sup>®</sup>, TERIL<sup>®</sup>)
- dexamethasone (OZURDEX<sup>®</sup>, MAXIDEX<sup>®</sup>, DECADRON<sup>®</sup>, BAYCADRON<sup>™</sup>)
- dexlansoprazole (DEXILANT<sup>®</sup>)
- esomeprazole (NEXIUM<sup>®</sup>, VIMOVO<sup>®</sup>)
- lansoprazole (PREVACID<sup>®</sup>)
- omeprazole (PRILOSEC<sup>®</sup>, ZEGERID<sup>®</sup>)
- oxcarbazepine (TRILEPTAL<sup>®</sup>)
- pantoprazole sodium (PROTONIX<sup>®</sup>)
- phenobarbital (LUMINAL<sup>®</sup>)
- phenytoin (DILANTIN<sup>®</sup>, DILANTIN-125<sup>®</sup>, PHENYTEK<sup>®</sup>)
- rabeprazole (ACIPHEX<sup>®</sup>)
- rifampin (RIFADIN<sup>®</sup>, RIFAMATE<sup>®</sup>, RIFATER<sup>®</sup>, RIMACTANE<sup>®</sup>)
- rifapentine (PRIFTIN<sup>®</sup>)
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort

#### **What should I tell my healthcare provider before taking ODEFSEY?**

##### **Before taking ODEFSEY, tell your healthcare provider if you:**

- have liver problems, including hepatitis B or C virus infection
- have kidney problems
- have a history of depression or suicidal thoughts
- have bone problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ODEFSEY can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking ODEFSEY.

**Pregnancy Registry:** There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take ODEFSEY.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - At least one of the medicines in ODEFSEY can pass to your baby in your breast milk. It is not known if the other medicines in ODEFSEY can pass into your breast milk.

Talk with your healthcare provider about the best way to feed your baby.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with ODEFSEY. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with ODEFSEY.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take ODEFSEY with other medicines.

### How should I take ODEFSEY?

- Take ODEFSEY exactly as your healthcare provider tells you to take it. ODEFSEY is taken by itself (not with other HIV-1 medicines) to treat HIV-1 infection.
- Take ODEFSEY 1 time each day with a meal.
- Do not change your dose or stop taking ODEFSEY without first talking with your healthcare provider. Stay under a healthcare provider's care when taking ODEFSEY.
- Do not miss a dose of ODEFSEY.
- If you take too much ODEFSEY, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your ODEFSEY supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to ODEFSEY and become harder to treat.

### What are the possible side effects of ODEFSEY?

#### ODEFSEY may cause serious side effects, including:

- **See "What is the most important information I should know about 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 reaction may need to be treated in a hospital.

#### **If you get a rash with any of the following symptoms, stop taking ODEFSEY and call your healthcare provider or get medical help right away:**

- 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
- **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
- **Change in liver enzymes.** People with a history of hepatitis B or C virus infection 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.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.
- **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 while you are taking 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).** Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- **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 “tea-colored” urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.

- **Bone problems** can happen in some people who take ODEFSEY. Bone problems may include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.

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

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

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ODEFSEY. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store ODEFSEY?**

- Store ODEFSEY below 86 °F (30 °C).
- Keep ODEFSEY in its original container.
- Keep the container tightly closed.

**Keep ODEFSEY and all medicines out of reach of children.**

#### **General information about the safe and effective use of ODEFSEY.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ODEFSEY for a condition for which it was not prescribed. Do not give ODEFSEY to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ODEFSEY that is written for health professionals.

For more information, call 1-800-445-3235 or go to [www.ODEFSEY.com](http://www.ODEFSEY.com).

#### **What are the ingredients in ODEFSEY?**

**Active ingredients:** emtricitabine, rilpivirine, and tenofovir alafenamide.

**Inactive ingredients:** croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 20, and povidone. The tablet film coating contains iron oxide black, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

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This Patient Information has been approved by the U.S. Food and Drug Administration

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