

ODEFSEY® Tablets

(200 mg emtricitabine /25 mg rilpivirine /25 mg tenofovir alafenamide)

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about ODEFSEY tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally and you should not pass it on to others.

It may harm them, even if their symptoms are the same as yours.

Medicines are sometimes prescribed for conditions that are not mentioned in this leaflet.

Keep this leaflet with your ODEFSEY medicine.

You may need to read it again.

What is ODEFSEY

How ODEFSEY works

ODEFSEY tablets consist of the following three medicines:

- emtricitabine (EMTRIVA®)
- rilpivirine (EDURANT®)
- tenofovir alafenamide

These are combined in one tablet to help control Human Immunodeficiency Virus (HIV) infection.

ODEFSEY helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply.

ODEFSEY lowers the amount of HIV in the blood (viral load). ODEFSEY may also help to increase the number of T cells (CD4⁺ cells), allowing your immune system to improve.

Lowering the amount of HIV in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

HIV infection destroys CD4 T cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) may develop.

ODEFSEY is for people who do not have a resistant HIV virus to ODEFSEY.

EMTRIVA® (emtricitabine) belongs to a group of antiviral medicines known as nucleoside and nucleotide reverse transcriptase inhibitors (NRTI).

EDURANT® (rilpivirine) belongs to a group of antiviral medicines known as non-nucleoside reverse transcriptase inhibitors (NNRTI).

Use in children and elderly

ODEFSEY is used to treat HIV-1 infection in adults and children 12 years of age and older.

ODEFSEY has not been studied in children under the age of 12 or weighing less than 35 kg.

Does ODEFSEY cure HIV or AIDS

ODEFSEY does not cure HIV infection or AIDS.

The long-term effects of ODEFSEY are not known at this time.

People taking ODEFSEY may still get opportunistic infections or other conditions that happen with HIV infection.

Opportunistic infections are infections that develop because the immune system is weakened. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium complex* (MAC) infection.

This medicine is only available from a pharmacist after it has been prescribed by a doctor who specialises in the treatment of HIV infection.

If you wish to continue receiving treatment with ODEFSEY it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

Does ODEFSEY reduce the risk of passing HIV to others

ODEFSEY does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood.

For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom of other barrier to lower the chance of sexual

contact with semen, vaginal secretions, or blood.

Never re-use or share needles.

Before you take ODEFSEY

When you must not take it

Together with your doctor, you need to decide whether ODEFSEY is right for you.

Do not take ODEFSEY if you are allergic to:

- emtricitabine
- rilpivirine
- tenofovir
- or any of the other ingredients of ODEFSEY.

The ingredients of ODEFSEY are listed in the Product Description section of this leaflet.

Do not take ODEFSEY if you are already taking any other medicines to treat HIV infection such as:

- tenofovir disoproxil fumarate
- emtricitabine
- lamivudine
- tenofovir alafenamide
- rilpivirine

Do not take ODEFSEY if you take:

- carbamazepine (e.g. Tegretol)
- oxycarbazepine (e.g. Trileptal)
- phenobarbital or phenytoin (e.g. Dilantin)
- rifampicin (e.g. Rifadin/Rimycin)
- rifapentine (e.g. Priftin)
- omeprazole (e.g. Losec)
- esomeprazole (e.g. Nexium)
- lansoprazole (e.g. Zopral)
- dexlansoprazole
- pantoprazole (e.g. Somac)
- rabeprazole (e.g. Pariet)
- St John's Wort or products containing St John's Wort

Do not take ODEFSEY to treat your HIV infection if you are also

taking adefovir dipivoxil to treat your hepatitis B virus (HBV) infection.

This is not a complete list of medicines that you should tell your doctor about.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- kidney problems or are undergoing kidney dialysis treatment.
- liver problems, including hepatitis B or C virus infection.

Tell your doctor if you are pregnant, or likely to become pregnant during your course of medication.

We do not know if ODEFSEY can harm your unborn child. You and your doctor will need to decide if ODEFSEY is right for you.

Tell your doctor if you are breastfeeding, or likely to breastfeed during your course of medication.

You should not breastfeed if you are HIV-positive because of the chance of passing the HIV virus to your baby. At least one of the active substances in this medicine (emtricitabine) have been found in breast milk at low concentrations. Talk with your doctor about the best way to feed your baby.

Taking other medicines

Some medicines may affect the levels of ODEFSEY or ODEFSEY may affect the levels of other medicines in the body when they are taken at the same time as ODEFSEY.

Your doctor may change your other medicines or change their doses. Other medicines, including herbal products may affect ODEFSEY.

For this reason, it is very important to let your doctor or

pharmacist know what medications, herbal supplements, or vitamins you are taking.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine.

Your doctor and your pharmacist can tell you if you can take these medicines with ODEFSEY.

Do not start any new medicines while you are taking ODEFSEY without first talking with your doctor or pharmacist.

How to take ODEFSEY

Take the exact amount of ODEFSEY your doctor has prescribed for you.

Never change the dose on your own.

Do not stop this medicine unless your healthcare provider tells you to stop.

How much to take

The usual dose is one ODEFSEY tablet orally, once daily.

Take ODEFSEY with food.

If you forget to take it

Do not miss a dose of ODEFSEY.

If you forget to take ODEFSEY, take your missed dose right away unless it is almost time for your next dose.

Do not take a double dose to make up for a forgotten dose.

Continue with your regular dosing schedule.

When your ODEFSEY supply starts to run low, get more from your doctor 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.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 13 11 26 (Australia) and 0800 764 766 (New Zealand) or go to the Accident and Emergency Department at your nearest hospital if you think you or anyone else may have taken too many ODEFSEY tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

While you are taking ODEFSEY

Things you must not do

Do not breastfeed. See “Before you start to take it.”

Avoid doing things that can spread HIV infection since ODEFSEY does not stop you from passing the HIV Infection to others.

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- **Do not have any kind of sex without protection.**

Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions, or blood.

Do not take ODEFSEY after the expiry or “use by” date (EXP) printed on the bottle.

If you take it after the expiry date has passed, it may not work as well.

Do not take ODEFSEY if the packaging is torn or shows signs of tampering.

Things to be careful of

Be careful driving or operating machinery until you know how ODEFSEY affects you.

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

Side Effects

Like all medicines, ODEFSEY can have side effects, although not everybody gets them. Some may be serious and need medical attention.

Check with your doctor as soon as possible if you have any problems while taking ODEFSEY, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Serious side effects

Lactic Acidosis

If you have any of the following symptoms after taking your medication, tell your doctor IMMEDIATELY or go to the Accident and Emergency Department at your nearest hospital.

- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you have stomach pain with nausea and vomiting
- you feel cold, especially in your arms and legs
- you feel dizzy or light-headed
- you have a fast or irregular heartbeat

These side effects may be due to a condition called lactic acidosis (build-up of an acid in the blood).

Lactic acidosis can be a medical emergency and may need to be treated in the hospital.

Serious Liver Problems (hepatotoxicity)

If you have any of the following

symptoms while taking your medication, tell your doctor IMMEDIATELY or go to the Accident and Emergency Department at your nearest hospital.

- your skin or the white part of your eyes turns yellow (jaundice)
- your urine turns dark
- your bowel movements (stools) turn light in colour
- you don't feel like eating food for several days or longer
- you feel sick to your stomach (nausea)
- you have lower stomach area (abdominal) pain

These side effects may be due to a condition called hepatotoxicity with liver enlargement (hepatomegaly) and fat deposits in the liver (steatosis) which sometimes occurs in patients taking anti-HIV medicines.

You may be more likely to get lactic acidosis or liver problems if you are female, very overweight (obese), or have been taking similar nucleoside analog-containing medicines, like ODEFSEY, for a long time.

Hepatic Flares

If you have HIV infection and HBV infection you should not stop your ODEFSEY treatment without first discussing this with your doctor. Your HBV may get worse (flare-up) if you stop taking ODEFSEY. A “flare-up” or “hepatic flare” is when your HBV infection suddenly returns in a worse way than before. You may require medical exams and blood tests for several months after stopping treatment. ODEFSEY is not approved for the treatment of HBV, so you must discuss your HBV therapy with your doctor.

Changes in body fat

Changes in body fat develop in some people receiving anti HIV-1 therapy. These changes may include an increased amount of fat in the upper back and neck (‘buffalo hump’), in the breasts and around

the trunk. Loss of fat from the legs, arms and face may also happen. The cause and long-term health effects of these fat changes are not known.

Signs and symptoms of inflammation

In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, which lets the body fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please tell your doctor immediately.

Allergy

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE ANY MORE ODEFSEY and tell your doctor IMMEDIATELY or go to the Accident and Emergency Department at your nearest hospital:

- skin troubles such as lumpy skin rash or "hives"
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- wheezing, chest pain or tightness
- fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation.

Common side effects

The most common side effect of ODEFSEY is nausea.

Other side effects include:

- diarrhoea
- fatigue
- headaches
- abdominal pain
- indigestion

- flatulence
- dizziness
- rash
- vomiting
- depression
- weight gain
- abnormal dreams and sleep issues
- insomnia
- decreased appetite

Talk to your doctor or pharmacist if you don't understand anything in this list.

This is not a complete list of side effects possible with ODEFSEY.

Ask your doctor or pharmacist for a more complete list of side effects of ODEFSEY and all the medicines you will take.

After taking ODEFSEY

Storage

Keep ODEFSEY tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep ODEFSEY tablets in a cool, dry place where it stays below 30°C.

Do not store ODEFSEY or any other medicine in a bathroom or near a sink.

Do not leave ODEFSEY in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep your ODEFSEY tablets in the bottle with the cap tightly closed until you take them.

If you take ODEFSEY tablets out of their pack they may not keep well.

Product Description

What the tablets look like

The 200/25/25 mg ODEFSEY tablets are oval-shaped, film-coated and grey in colour.

Each tablet is debossed with "GSI" on one side and the number "255" on the other side.

ODEFSEY tablets are supplied in bottles containing 30 tablets.

Ingredients

Each ODEFSEY tablet contains the active ingredients:

- emtricitabine
- rilpivirine
- tenofovir alafenamide

Each ODEFSEY tablet also contains the following inactive ingredients:

- lactose
- microcrystalline cellulose
- povidone
- polysorbate 20
- croscarmellose sodium
- magnesium stearate

Film-coating:

- polyvinyl alcohol (E1203)
- titanium dioxide (E171)
- polyethylene glycol
- talc (E553b)
- iron oxide black (E172)

Sponsor

ODEFSEY tablets are supplied in Australia by:

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

In New Zealand:

Gilead Sciences (NZ)
c/- PricewaterhouseCoopers
Level 8 PricewaterhouseCoopers
Tower
188 Quay Street
Auckland 1010

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