

Package leaflet: Information for the user

Odefsey 200 mg/25 mg/25 mg film-coated tablets emtricitabine/rilpivirine/tenofovir alafenamide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Odefsey is and what it is used for
2. What you need to know before you take Odefsey
3. How to take Odefsey
4. Possible side effects
5. How to store Odefsey
6. Contents of the pack and other information

1. What Odefsey is and what it is used for

Odefsey is an antiviral medicine used to treat infection by the **Human Immunodeficiency Virus (HIV)**. It is a single tablet that contains a combination of three active substances: **emtricitabine, rilpivirine and tenofovir alafenamide**. Each of these active substances works by interfering with an enzyme called ‘reverse transcriptase’, which is essential for the HIV-1 virus to multiply.

Odefsey reduces the amount of HIV in your body. This will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

Odefsey is used in adults and adolescents aged 12 years and older, who weigh at least 35 kg.

2. What you need to know before you take Odefsey

Do not take Odefsey

- **If you are allergic to emtricitabine, rilpivirine, tenofovir alafenamide** or any of the other ingredients of this medicine (listed in section 6).
- **If you are currently taking any of the following medicines:**
 - **carbamazepine, oxcarbazepine, phenobarbital and phenytoin** (used to treat epilepsy and prevent seizures)
 - **rifabutin, rifampicin and rifapentine** (used to treat some bacterial infections such as tuberculosis)
 - **omeprazole, dexlansoprazole, lansoprazole, rabeprazole, pantoprazole and esomeprazole** (used to prevent and treat stomach ulcers, heartburn, acid reflux disease)
 - **dexamethasone** (a corticosteroid medicine used to treat inflammation and suppress the immune system) when taken by mouth or injected (except as a single dose treatment)

- **products that contain St. John's wort** (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)

→ If this applies to you, **do not take Odefsey and tell your doctor immediately.**

Warnings and precautions

You must remain under the care of your doctor while taking Odefsey.

This medicine is not a cure for HIV infection. While taking Odefsey you may still develop infections or other illnesses associated with HIV infection.

Talk to your doctor before taking Odefsey:

- **If you have liver problems or a history of liver disease, including hepatitis.** Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you.
- **If you have hepatitis B infection,** liver problems may become worse after you stop taking Odefsey. It is important not to stop taking Odefsey without talking to your doctor: see section 3, *Do not stop taking Odefsey.*
- If you are taking any medicines that may cause a life-threatening irregular heartbeat (*Torsades de Pointes*).
- **If you have had kidney disease or if tests have shown problems with your kidneys.** Your doctor may order blood tests to monitor how your kidneys work when starting and during treatment with Odefsey.

While you are taking Odefsey

Once you start taking Odefsey, look out for:

- **Signs of inflammation or infection**
- **Joint pain, stiffness or bone problems**

→ **If you notice any of these symptoms, tell your doctor immediately.** For more information see section 4, *Possible side effects.*

There is a possibility that you may experience kidney problems when taking Odefsey over a long period of time (see *Warnings and precautions*).

Children and adolescents

Do not give this medicine to children aged 11 years or under, or weighing less than 35 kg. The use of Odefsey in children aged 11 years or under or weighing less than 35 kg has not yet been studied.

Other medicines and Odefsey

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Odefsey may interact with other medicines. As a result, the amounts of Odefsey or other medicines in your blood may be affected. This may stop your medicines from working properly, or may make any side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels.

Medicines that must never be taken with Odefsey:

- **carbamazepine, oxcarbazepine, phenobarbital and phenytoin** (used to treat epilepsy and prevent seizures)
- **rifabutin, rifampicin and rifapentine** (used to treat some bacterial infections such as tuberculosis)
- **omeprazole, dexlansoprazole, lansoprazole, rabeprazole, pantoprazole and esomeprazole** (used to prevent and treat stomach ulcers, heartburn, acid reflux disease)
- **dexamethasone** (a corticosteroid medicine used to treat inflammation and suppress the immune system) when taken by mouth or injected (except as a single dose treatment)
- **products that contain St. John's wort** (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)

→ If you are taking any of these medicines, **do not take Odefsey and tell your doctor immediately.**

Other types of medicine:

Talk to your doctor if you are taking:

- **Any medicines used for treating HIV**
- **Any medicines containing:**
 - tenofovir alafenamide
 - tenofovir disoproxil
 - lamivudine
 - adefovir dipivoxil
- **Antibiotics used to treat bacterial infections** containing:
 - clarithromycin
 - erythromycin

These medicines can increase the amount of rilpivirine and tenofovir alafenamide (components of Odefsey) in your blood. Your doctor will give you a different medicine.
- **Antifungal medicines used to treat fungal infections:**
 - ketoconazole
 - fluconazole
 - itraconazole
 - posaconazole
 - voriconazole

These medicines can increase the amount of rilpivirine and tenofovir alafenamide (components of Odefsey) in your blood. Your doctor will give you a different medicine.
- **Medicines for stomach ulcers, heartburn or acid reflux** such as:
 - **antacids** (aluminium/magnesium hydroxide or calcium carbonate)
 - **H₂-antagonists** (famotidine, cimetidine, nizatidine or ranitidine)

These medicines can decrease the amount of rilpivirine (a component of Odefsey) in your blood. If you are taking one of these medicines your doctor will either give you a different medicine, or recommend how and when you take that medicine:

 - **If you are taking an antacid**, take it at least 2 hours before or at least 4 hours after Odefsey.
 - **If you are taking an H₂-antagonist**, take it at least 12 hours before or at least 4 hours after Odefsey. H₂-antagonists can only be taken once a day if you take Odefsey. H₂-antagonists should not be taken in a twice a day regimen. Talk to your doctor about an alternative regimen (see *How to take Odefsey*).

- **Ciclosporin**, a medicine used to reduce the strength of the body's immune system: This medicine can increase the amount of rilpivirine and tenofovir alafenamide (components of Odefsey) in your blood. Your doctor will give you a different medicine.
- **Methadone**, a medicine used to treat opiate addiction, as your doctor may need to change your methadone dose.
- **Dabigatran etexilate**, a medicine used to treat heart conditions, as your doctor may need to monitor the levels of this medicine in your blood.

→ **Tell your doctor if you are taking any of these medicines.** Do not stop your treatment without contacting your doctor.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- **Use effective contraception** while taking Odefsey.

Ask your doctor or pharmacist for advice before taking any medicine when pregnant.

If you have taken Odefsey during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took nucleoside reverse transcriptase inhibitors (NRTIs) during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Do not breast-feed during treatment with Odefsey. This is because some of the active substances in this medicine pass into human breast milk.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

Driving and using machines

Do not drive or operate machines if you feel tired, sleepy or dizzy after taking your medicine.

Odefsey contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

→ If any of these applies to you, **talk to your doctor before taking Odefsey.**

3. How to take Odefsey

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults: one tablet each day with food

Adolescents 12 years of age and older, who weigh at least 35 kg: one tablet each day with food

It is important to take Odefsey with food to get the right levels of active substance in your body. A nutritional drink alone does not replace food.

It is recommended not to chew, crush or split the tablet due to the bitter taste.

If you are taking an antacid such as aluminium/magnesium hydroxide, or calcium carbonate, take it at least 2 hours before or at least 4 hours after Odefsey.

If you are taking an H₂-antagonist such as famotidine, cimetidine, nizatidine or ranitidine, take it at least 12 hours before or at least 4 hours after Odefsey. H₂-antagonists can only be taken once a day if you take Odefsey. H₂-antagonists should not be taken twice a day. Talk to your doctor about an alternative regimen.

If you are on dialysis, take your daily dose of Odefsey following completion of dialysis.

If you take more Odefsey than you should

If you accidentally take more than the recommended dose of Odefsey you may be at increased risk of experiencing possible side effects with this medicine (see section 4, *Possible side effects*).

Contact your doctor or nearest emergency department immediately for advice. Keep or take the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Odefsey

It is important not to miss a dose of Odefsey.

If you do miss a dose:

- **If you notice within 12 hours** of the time you usually take Odefsey, you must take the tablet as soon as possible. Always take the tablet with food. Then take the next dose as usual.
- **If you notice 12 hours or more** after the time you usually take Odefsey, then do not take the missed dose. Wait and take the next dose, with food, at your usual time.

If you vomit less than 4 hours after taking Odefsey, take another tablet with food. **If you vomit more than 4 hours after taking Odefsey** you do not need to take another tablet until your next regularly scheduled tablet.

Do not stop taking Odefsey

Do not stop taking Odefsey without talking to your doctor. Stopping Odefsey can seriously affect your response to future treatment. If Odefsey is stopped for any reason, speak to your doctor before you restart taking Odefsey tablets.

When your supply of Odefsey starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The disease may then become harder to treat.

If you have both HIV infection and hepatitis B, it is especially important not to stop your Odefsey treatment without talking to your doctor first. You may require blood tests for several months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of your hepatitis, which may be life-threatening.

→ **Tell your doctor immediately** about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects: tell a doctor immediately

- **Any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after HIV treatment is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.
- **Autoimmune disorders**, when the immune system attacks healthy body tissue, may also occur after you start taking medicines for HIV infection. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
 - muscle weakness
 - weakness beginning in the hands and feet and moving up towards the trunk of the body
 - palpitations, tremor or hyperactivity

→ **If you notice these or any symptoms of inflammation or infection, tell your doctor immediately.**

Very common side effects

(may affect more than 1 in 10 people)

- difficulty sleeping (*insomnia*)
- headache
- dizziness
- feeling sick (*nausea*)

Tests may also show:

- increased levels of cholesterol and/or pancreatic amylase (a digestive enzyme) in the blood
- increased levels of liver enzymes in the blood

Common side effects

(may affect up to 1 in 10 people)

- decreased appetite
- depression
- abnormal dreams
- sleep disorders
- depressed mood
- feeling sleepy (somnolence)
- tiredness
- stomach pain or discomfort
- being sick (*vomiting*)

- feeling bloated
- dry mouth
- wind (*flatulence*)
- diarrhoea
- rash

Tests may also show:

- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- low platelet count (a type of blood cell involved in clotting blood)
- decrease in haemoglobin in your blood
- increased fatty acids (*triglycerides*), bilirubin or lipase in the blood

Uncommon side effects

(may affect up to 1 in 100 people)

- signs or symptoms of inflammation or infection
- low red blood cell count (*anaemia*)
- severe skin reactions including rash accompanied by fever, swelling and liver problems
- problems with digestion resulting in discomfort after meals
- swelling of the face, lips, tongue or throat (*angioedema*)
- itching (*pruritus*)
- hives (*urticaria*)
- joint pain (*arthralgia*)

→ **If any of the side effects get serious tell your doctor.**

Other effects that may be seen during HIV treatment

The frequency of the following side effects is not known (frequency cannot be estimated from the available data).

- **Bone problems.** Some patients taking combination antiretroviral medicines such as Odefsey may develop a bone disease called *osteonecrosis* (death of bone tissue caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a very weak immune system, and being overweight, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are:
 - joint stiffness
 - joint aches and pains (especially of the hip, knee and shoulder)
 - difficulty with movement

→ **If you notice any of these symptoms tell your doctor.**

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the *Yellow Card Scheme*, Website: www.mhra.gov.uk/yellowcard or search for *MHRA Yellow Card* in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Odefsey

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after {EXP}. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Odefsey contains

The active substances are emtricitabine, rilpivirine and tenofovir alafenamide. Each Odefsey tablet contains 200 mg of emtricitabine, rilpivirine hydrochloride equivalent to 25 mg of rilpivirine and tenofovir alafenamide fumarate equivalent to 25 mg of tenofovir alafenamide.

The other ingredients are

Tablet core:

Croscarmellose sodium, lactose (as monohydrate), magnesium stearate, microcrystalline cellulose, polysorbate 20, povidone.

Film-coating:

Macrogol, polyvinyl alcohol, talc, titanium dioxide (E171), iron oxide black (E172).

What Odefsey looks like and contents of the pack

Odefsey is a grey, capsule-shaped, film-coated tablet debossed on one side with “GSI” and “255” on the other side. Odefsey comes in bottles of 30 tablets and in packs made up of 3 bottles, each containing 30 tablets. Each bottle contains a silica gel desiccant that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

Not all pack sizes may be marketed.

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