

Patient leaflet in accordance with the Pharmacists' (Products) Regulations - 1986

This medicine is to be supplied by doctor's prescription only

Descovy[®] 200 mg/10 mg
Descovy[®] 200 mg/25 mg
Film-coated tablets

Active ingredients: Each tablet contains –

- Descovy 200 mg/10 mg:
emtricitabine 200mg
tenofovir alafenamide 10mg
- Descovy 200 mg/25 mg:
emtricitabine 200mg
tenofovir alafenamide 25mg

Inactive and allergenic substances: see section 6 "*Additional information*".

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This leaflet contains essential information about this medicine. If you have any further questions, ask your doctor or pharmacist. Keep this leaflet. You may need to read it again. This medicine has been prescribed only for the treatment of your disease. 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.

This medicine is intended for adults and adolescents 12 years of age and older, who weigh at least 35 kg.

1. What is the medicine intended for

Descovy in combination with other medicines is for the **treatment of human immunodeficiency virus 1 (HIV-1) infection** in adults and adolescents 12 years of age and older, who weigh at least 35 kg.

Descovy blocks the action of the reverse transcriptase enzyme, which is essential for the virus to multiply. Descovy, therefore, reduces the amount of HIV in your body.

Therapeutic group:

Descovy contains two active substances:

- **emtricitabine**, is a nucleoside with antiretroviral activity which inhibits the reverse transcriptase enzyme (NRTI)
- **tenofovir alafenamide**, is a nucleotide with antiretroviral activity which inhibits the reverse transcriptase enzyme (NtRTI)

2. Before taking the medicine

X Do not take this medicine

- **If you are allergic to emtricitabine, tenofovir alafenamide** or any of the other ingredients of this medicine (see section 6 "Additional Information").

Special warnings relating to the use of the medicine

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

You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people. This medicine is not a cure for HIV infection. While taking Descovy you may still develop infections or other illnesses associated with HIV infection.

Talk to your doctor before taking Descovy:

- **If you have liver problems or have suffered from 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 Descovy. Do not stop taking Descovy without talking to your doctor: see section 3, *Do not stop taking Descovy*.

- Your doctor may choose to not prescribe Descovy to you if your virus has a certain resistance mutation, as Descovy may not be able to reduce the amount of HIV in your body as effectively.
- **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 Descovy.

While you are taking the medicine

Once you start taking Descovy, 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, *Side effects*.

Although kidney problems have not been observed with Descovy, there is a possibility that you may experience kidney problems when taking Descovy over a long period of time (see *Warnings and precautions*).

Other medicines and Descovy

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines including non prescription medicines and dietary supplements. Descovy may interact with other medicines. As a result, the levels of Descovy or other medicines in your blood may change. 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 used in treating hepatitis B infection:

You should not take Descovy with medicines containing:

- **tenofovir alafenamide**
- **tenofovir disoproxil**
- **lamivudine**
- **adefovir dipivoxil**

→ **Tell your doctor** if you are taking any of these medicines.

Other types of medicine:

Talk to your doctor if you are taking:

- **antibiotics**, used to treat bacterial infections including tuberculosis, containing:
 - rifabutin, rifampicin, and rifapentine
- **antiviral medicines used to treat HIV:**
 - emtricitabine and tipranavir
- **anticonvulsants**, used to treat epilepsy, such as:
 - carbamazepine, oxcarbazepine, phenobarbital and phenytoin
- **herbal remedies** used to treat depression and anxiety containing:
 - St. John's wort (*Hypericum perforatum*)

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

Taking the medicine and food

Take with or without food.

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 or pharmacist for advice before taking this medicine.
- Tell your doctor immediately if you become pregnant and ask about the potential benefits and risks of your antiretroviral therapy to you and your child.

If you have taken Descovy 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 NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Do not breast-feed during treatment with Descovy. This is because one of the active substances in this medicine passes into breast milk. It is recommended that you do not breast-feed to avoid passing the virus to the baby through breast milk.

Driving and using machines

Descovy can cause dizziness. If you feel dizzy when taking Descovy, do not drive and do not use any tools or machines.

Children and adolescents

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

Descovy contains sodium

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

3. How to take Descovy

Always take this medicine exactly as your doctor has told you.

The dosage and treatment will be determined by your doctor only. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults: one tablet each day, with or without food

Adolescents 12 years of age and older, who weigh at least 35 kg: one tablet each day with or without food

Do not exceed the recommended dose.

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

If you have difficulty swallowing the tablet whole, you can split it in half. Take both halves of the tablet one after the other to get the full dose. Do not store the split tablet.

Always take the dose recommended by your doctor. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.

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

If you take more medicine than you should

If you accidentally take more than the recommended dose of Descovy, or if a child has accidentally swallowed the medicine, you may be at increased risk of experience possible side effects with this medicine (see section 4, *Side effects*). Contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take the medicine

It is important not to miss a dose of Descovy.

If you do miss a dose:

- **If you notice within 18 hours** of the time you usually take Descovy, you must take the tablet as soon as possible. Then take the next dose as usual.
- **If you notice 18 hours or more** after the time you usually take Descovy, then do not take the missed dose. Wait and take the next dose at your usual time.

If you vomit less than 1 hour after taking Descovy, take another tablet.

Do not stop taking the medicine

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

When your supply of Descovy 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 few days. The disease may then become harder to treat.

If you have both HIV infection and hepatitis B, it is very important not to stop taking Descovy 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 may lead to worsening of 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.

Do not take medicines in the dark. Check the label and the dose every time you take a medicine. Wear glasses if you need them.

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

4. Side effects

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

Do not be alarmed by reading the list of side effects. You may not experience any of them.

Possible serious side effects: tell a doctor immediately

- **Any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and who have had opportunistic infections in the past (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after antiretroviral 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** (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 the side effects described above, tell your doctor immediately.**

Very common side effects

(may affect more than 1 in 10 people)

- feeling sick (*nausea*)

Common side effects

(may affect up to 1 in 10 people)

- abnormal dreams
- headache
- dizziness
- diarrhoea
- vomiting
- stomach pain
- wind (*flatulence*)
- rash
- tiredness (*fatigue*)

Uncommon side effects

(may affect up to 1 in 100 people)

- low red blood cell count (*anaemia*)
- problems with digestion resulting in discomfort after meals (*dyspepsia*)
- 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 Descovy 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 report any side effects to the Ministry of Health by clicking on the link "Report side effects due to medical treatment" that is located on the Ministry of Health homepage (www.health.gov.il) which redirects to the online form for reporting side effects or by clicking on the link: <https://sideeffects.health.gov.il>.

Additionally, you can also report any side effects to the Registration Holder via email: DrugSafety.Israel@gilead.com

5. How to store the medicine

Prevent poisoning! Keep this medicine out of the sight and reach of children and/or babies. In this way you will prevent poisoning. Do not induce vomiting without a doctor's express instruction.

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.

There are no special storage conditions. It is recommended to store at room temperature.

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. Additional Information

What the medicine contains

The active substances are emtricitabine and tenofovir alafenamide.

- Descovy 200 mg/10 mg:

Each Descovy film-coated tablet contains 200 mg of emtricitabine and tenofovir alafenamide fumarate equivalent to 10 mg of tenofovir alafenamide.

- Descovy 200 mg/25 mg:

Each Descovy film-coated tablet contains 200 mg of emtricitabine and tenofovir alafenamide fumarate equivalent to 25 mg of tenofovir alafenamide.

The other ingredients are

Tablet core:

Microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

- Descovy 200 mg/10 mg:

Film-coating:

Polyvinyl alcohol-part hydrolyzed, titanium dioxide, macrogol/PEG 3350, talc, iron oxide black

- Descovy 200 mg/25 mg:

Film-coating:

Polyvinyl alcohol-part hydrolyzed, titanium dioxide, macrogol/PEG 3350, talc, FD&C Blue #2/indigo carmine aluminium lake.

What does the medicine look like and contents of the pack

- Descovy 200 mg/10 mg:
Descovy film-coated tablets are grey, rectangular-shaped tablets of dimensions approximately 12.5 mm x 6.4 mm debossed on one side with “GSI” and the number “210” on the other side of the tablet.
- Descovy 200 mg/25 mg:
Descovy film-coated tablets are blue, rectangular-shaped tablets of dimensions approximately 12.5 mm x 6.4 mm debossed on one side with “GSI” and the number “225” on the other side of the tablet.

Descovy comes in bottles of 30 tablets (with 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.

The following pack size is available: outer cartons containing 1 bottle of 30 film-coated tablets.

Registration Holder: Gilead Sciences Israel Ltd., 4 HaHarash Street, Hod Hasharon, 4524075, Israel

Manufacturer: Gilead Sciences Ireland UC, IDA Business & Technology Park, Carrigtohill, Country Cork, Ireland

The medicine’s registration no. in the national register of medicines at the Ministry of Health:

- Descovy 200mg/10mg: 34949
- Descovy 200mg/25mg: 34950

For simplicity and ease of reading, this leaflet was phrased in the masculine. Nevertheless, the medicine is intended for both sexes.

Revised in April 2022 according to MoH guidelines.

Reference: EU label from May 2021.

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