

## Package leaflet: Information for the user

### Descovy 200 mg/25 mg film-coated tablets emtricitabine/tenofovir alafenamide

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

#### **1. What Descovy is and what it is used for**

Descovy contains two active substances:

- **emtricitabine**, an antiretroviral medicine of a type known as a nucleoside reverse transcriptase inhibitor (NRTI)
- **tenofovir alafenamide**, an antiretroviral medicine of a type known as a nucleotide reverse transcriptase inhibitor (NtRTI)

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.

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.

#### **2. What you need to know before you take Descovy**

##### **Do not take Descovy:**

- **If you are allergic to emtricitabine, tenofovir alafenamide** or any of the other ingredients of this medicine (listed in section 6 of this leaflet).

#### **Warnings and precautions**

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 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 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 not prescribe Descovy to you if the virus has a K65R mutation.

### **While you are taking Descovy**

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, *Possible 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.

### **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.

### **Other medicines and Descovy**

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.** Descovy may interact with other medicines. As a result, the amounts 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.

### **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.

### **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. 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 chew, crush or split the 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 Descovy than you should**

If you take more than the recommended dose of Descovy you may be at higher risk of side effects of this medicine (see section 4, *Possible side effects*).

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

### **If you forget to take Descovy**

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 Descovy**

**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 short time. 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.

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 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 also report side effects directly via the national reporting system:

### **United Kingdom**

*Yellow Card Scheme*

*Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store*

### **Ireland**

*HPRA Pharmacovigilance*

*Website: [www.hpra.ie](http://www.hpra.ie)*

### **Malta**

*ADR Reporting*

*Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)*

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

## **5. How to store Descovy**

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 Descovy contains**

**The active substances are** emtricitabine and tenofovir alafenamide. 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.

*Film-coating:*

Polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, indigo carmine aluminium lake (E132).

### **What Descovy looks like and contents of the pack**

Descovy film-coated tablets are blue, rectangular-shaped tablets, 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 sizes are available: outer cartons containing 1 bottle of 30 film-coated tablets and outer cartons containing 60 (2 bottles of 30) and 90 (3 bottles of 30) film-coated tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Gilead Sciences Ireland UC  
Carrigtohill  
County Cork, T45 DP77  
Ireland

**Manufacturer:**

Gilead Sciences Ireland UC  
IDA Business & Technology Park  
Carrigtohill  
County Cork  
Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**België/Belgique/Belgien**

Gilead Sciences Belgium SPRL-BVBA  
Tél/Tel: + 32 (0) 24 01 35 50

**Lietuva**

Gilead Sciences Poland Sp. z o.o.  
Tel: +48 22 262 8702

**България**

Gilead Sciences Ireland UC  
Тел.: + 353 (0) 1 686 1888

**Luxembourg/Luxemburg**

Gilead Sciences Belgium SPRL-BVBA  
Tél/Tel: + 32 (0) 24 01 35 50

**Česká republika**

Gilead Sciences s.r.o.  
Tel: + 420 910 871 986

**Magyarország**

Gilead Sciences Ireland UC  
Tel: + 353 (0) 1 686 1888

**Danmark**

Gilead Sciences Sweden AB  
Tlf: + 46 (0) 8 5057 1849

**Malta**

Gilead Sciences Ireland UC  
Tel: + 353 (0) 1 686 1888

**Deutschland**

Gilead Sciences GmbH  
Tel: + 49 (0) 89 899890-0

**Nederland**

Gilead Sciences Netherlands B.V.  
Tel: + 31 (0) 20 718 36 98

**Eesti**

Gilead Sciences Poland Sp. z o.o.  
Tel: +48 22 262 8702

**Norge**

Gilead Sciences Sweden AB  
Tlf: + 46 (0) 8 5057 1849

**Ελλάδα**

Gilead Sciences Ελλάς Μ.ΕΠΕ.  
Τηλ: + 30 210 8930 100

**Österreich**

Gilead Sciences GesmbH  
Tel: + 43 1 260 830

**España**

Gilead Sciences, S.L.  
Tel: + 34 91 378 98 30

**Polska**

Gilead Sciences Poland Sp. z o.o.  
Tel: +48 22 262 8702

**France**

Gilead Sciences  
Tél: + 33 (0) 1 46 09 41 00

**Portugal**

Gilead Sciences, Lda.  
Tel: + 351 21 7928790

**Hrvatska**

Gilead Sciences Ireland UC  
Tel: + 353 (0) 1 686 1888

**Ireland**

Gilead Sciences Ireland UC.  
Tel: + 353 (0) 214 825 999

**Ísland**

Gilead Sciences Sweden AB  
Sími: + 46 (0) 8 5057 1849

**Italia**

Gilead Sciences S.r.l.  
Tel: + 39 02 439201

**Κύπρος**

Gilead Sciences Ελλάς Μ.ΕΠΕ.  
Τηλ: + 30 210 8930 100

**Latvija**

Gilead Sciences Poland Sp. z o.o.  
Tel: +48 22 262 8702

**România**

Gilead Sciences Ireland UC  
Tel: + 353 (0) 1 686 1888

**Slovenija**

Gilead Sciences Ireland UC  
Tel: + 353 (0) 1 686 1888

**Slovenská republika**

Gilead Sciences Slovakia s.r.o.  
Tel: + 421 232 121 210

**Suomi/Finland**

Gilead Sciences Sweden AB  
Puh/Tel: + 46 (0) 8 5057 1849

**Sverige**

Gilead Sciences Sweden AB  
Tel: + 46 (0) 8 5057 1849

**United Kingdom**

Gilead Sciences Ltd.  
Tel: + 44 (0) 8000 113 700

**This leaflet was last revised in 05/2020.**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>.