PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a physician's prescription only

Dovato

Film-Coated Tablets

Each tablet contains:
dolutegravir (as sodium) 50 mg
lamivudine 300 mg

For the list of inactive and allergenic ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Dovato is indicated for the treatment of HIV-1 (human immunodeficiency virus) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitors class or to lamivudine, and with viral load that does not exceed 500,000 copies per mL.

Therapeutic group
Dovato contains two active ingredients used to treat human immunodeficiency virus (HIV): dolutegravir and lamivudine. Dolutegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*, and lamivudine belongs to a group of anti-retroviral medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.
Dovato does not cure HIV infection; it keeps the amount of virus in your body at a low level. This helps maintain the number of CD4 cells in your blood. CD4 cells are a type of white blood cells that are important in helping your body fight infection.
Not everyone responds to treatment with Dovato in the same way. The physician will monitor the effectiveness of your treatment.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are **hypersensitive** (allergic) to dolutegravir or lamivudine or to any of the other ingredients contained in the medicine (listed in section 6).
- you are taking a medicine called **fampridine**, used to treat multiple sclerosis.

→ **Tell the physician** if you think any of these apply to you**.**

Special warnings regarding use of the medicine

Some people taking Dovato or other combination treatments for HIV are more at risk of developing serious side effects than others. You need to be aware of the extra risks:

- if you have moderate or severe liver disease
- if you have ever had a liver disease, including hepatitis B or C (if you have hepatitis B, do not stop using Dovato without consulting with your physician, as your hepatitis may come back)
- if you have a kidney problem

→ **Talk to your physician before using Dovato** if any of these apply to you. You may need additional check-ups, including blood tests, while you are taking your medicine. See section 4 – "Side effects" for more information.

Allergic reactions

Dovato contains dolutegravir. Dolutegravir can cause a serious allergic reaction known as a *hypersensitivity reaction*. You need to know about important signs and symptoms to look out for while you are taking Dovato.

→ **Read the information** "Allergic reactions" in section 4 of this leaflet.

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. These include:

- symptoms of infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you are taking Dovato.

→ **Read the information "Other possible side effects" in section 4** of this leaflet.

Children and adolescents

This medicine is not intended for use in children under 12 years of age and in adolescents weighing less than 40 kg, because it has not been studied in these patients.

Drug interactions

If you are taking, if you have recently taken, or if you plan to take other medicines, including non-prescription medicines and nutritional

supplements, tell the physician or pharmacist.
Do not take Dovato with the following medicine:
- fampridine, used to treat **multiple sclerosis.**

Some medicines can affect how Dovato works or make it more likely that you will experience side effects. Dovato can also affect how some other medicines work.
Tell your physician if you are taking any of the medicines from the following list:
- metformin, to treat **diabetes**
- medicines called **antacids**, to treat **indigestion and heartburn. Do not take an antacid** during the 6 hours before you take Dovato, or for at least 2 hours after you take it
- nutritional supplements or multivitamins containing calcium, iron or magnesium. **If you take Dovato with food,** you can take nutritional supplements or multivitamins containing calcium, iron or magnesium at the same time as Dovato. **If you do not take Dovato with food, do not take a nutritional supplement or multivitamin containing calcium, iron or magnesium** during the 6 hours before you take Dovato, or for at least 2 hours after you take it
- emtricitabine, etravirine, efavirenz, nevirapine or tipranavir/ritonavir, to treat **HIV infection**
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
- cladribine, used to treat **leukaemia or multiple sclerosis**
- rifampicin, to treat tuberculosis (TB) and other **bacterial infections**
- phenytoin and phenobarbital, to treat **epilepsy**
- oxcarbazepine and carbamazepine, to treat **epilepsy** or **bipolar disorder**
- **St. John's wort** (*Hypericum perforatum*), a herbal medicine to treat **depression.**

→ **Tell the physician or pharmacist** if you are taking any of these medicines. The physician may decide to adjust your dose or decide that you need extra check-ups.

Pregnancy and breast-feeding

Pregnancy
If you are pregnant, think you may be pregnant, or if you are planning to become pregnant:
→ **Consult your physician** about the risks and benefits of taking Dovato.
Inform the physician immediately if you become pregnant or are planning to become pregnant. Your physician will review your treatment. Do not stop taking Dovato without consulting your physician, as this may harm you and your unborn child.

Breast-feeding

Breast-feeding is **not recommended** in women living with HIV because HIV infection can be passed on to the baby via breast milk.
A small amount of the ingredients in Dovato can also pass into your breast milk.
If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your physician** as soon as possible.

Driving and operating machinery
Dovato can make you dizzy, and have other side effects that make you less alert.
→ Do not drive or operate machinery unless you are sure you are not affected.

Important information about some of the ingredients of the medicine
This medicine contains less than 1 mmol sodium (23 mg) per tablet; therefore, it is essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the physician only.

The recommended dosage is generally:
- The recommended dosage is **one tablet** of Dovato **once a day.**

Swallow the tablet with a little liquid. Dovato can be taken with or without food.
There is no information regarding crushing/halving/chewing.

Use in adolescents
Adolescents aged 12 to 17 years weighing at least 40 kg can take the adult dose of one tablet, once a day.

Do not exceed the recommended dosage.

If you accidentally took a higher dosage
If you took too many Dovato tablets, **refer to a physician or pharmacist for advice.** If possible, show them the Dovato package.
If a child accidentally swallowed the medicine, immediately refer to a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine
If you miss a dose, take it as soon as you remember. However, if your next dose needs to be taken within 4 hours, skip the missed dose and take the next dose at the usual time. Then, continue with your treatment as usual.
→ **Do not take a double dose** to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the physician.

Do not stop taking Dovato without consulting your physician
Take Dovato for as long as your physician recommends it. Do not stop unless

your physician tells you to. Stopping Dovato can affect your health and how future treatment works.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult a physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dovato may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them. **It is very important to talk to your physician about any changes in your health.**

Allergic reactions
Dovato contains dolutegravir. Dolutegravir can cause a serious allergic reaction known as a *hypersensitivity reaction*.
This is an uncommon reaction (may occur in up to 1 in 100 people) in people taking dolutegravir.
If you develop any of the following symptoms:
- skin rash
- fever
- lack of energy (*fatigue*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- muscle or joint aches.

→ **Refer to a physician straight away.** Your physician may decide to carry out tests to check your liver, kidneys or blood, and may instruct you to stop taking Dovato.

Very common side effects
These may affect **more than 1 in 10 people:**
- headache
- diarrhoea
- nausea.

Common side effects
These may affect **up to 1 in 10 people:**
- depression (feelings of deep sadness and unworthiness)
- rash
- itching (*pruritus*)
- vomiting
- abdominal pain or discomfort
- weight gain
- wind (*flatulence*)
- dizziness

- feeling drowsy
- difficulty sleeping (*insomnia*)
- abnormal dreams
- lack of energy (*fatigue*)
- hair loss
- anxiety
- joint pain
- muscle pain.

Common side effects that may show up in blood tests:
- increase in the level of liver enzymes (*aminotransferases*)
- increase in the level of enzymes produced in the muscles (*creatine phosphokinase*).

Uncommon side effects
These may affect **up to 1 in 100 people:**
- inflammation of the liver (*hepatitis*)
- suicidal attempt (particularly in patients who have had depression or mental health problems before).
- suicidal thoughts (particularly in patients who have had depression or mental health problems before)
- panic attack.

Uncommon side effects that may show up in blood tests:
- a decreased number of cells involved in blood clotting (*thrombocytopenia*)
- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia*).

Rare side effects
These may affect **up to 1 in 1,000 people:**
- liver failure (signs may include yellowing of the skin and the whites of the eyes or unusually dark urine)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue
- suicide (particularly in patients who have had depression or mental health problems before).

→ **Tell your physician immediately** if you experience any mental health problems (see also other mental health problems above).

Rare side effects that may show up in blood tests:
- increase in bilirubin (a test of liver function)
- increase in the levels of an enzyme called *amylase.*

Very rare side effects
These may affect **up to 1 in 10,000 people:**

- lactic acidosis (excess lactic acid in the blood)
- numbness, tingly feelings in the skin (like “pins and needles”)
- sensation of weakness in the limbs.

A very rare side effect that may show up in blood tests:
- failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

Side effects whose frequency is not known
Cannot be estimated from the available data:
- a condition where red blood cells do not form properly (*sideroblastic anaemia*).

Other possible side effects
People taking combination therapy for HIV may suffer from other side effects.

Symptoms of infection and inflammation
People with advanced HIV infection or AIDS have weak immune systems, and are more likely to develop serious infections (*opportunistic infections*). Such infections may have been “silent” and not detected by the weak immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, plus some of the following:
- headache
- stomach ache
- difficulty breathing.

In rare cases, as the immune system becomes stronger, it can also attack healthy body tissue (*autoimmune disorders*). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection. Symptoms may include:
- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body.

If you develop any symptoms of infection or if you notice any of the symptoms above:
→ **Tell your physician immediately.** Do not take other medicines for the infection without your physician’s advice.

Joint pain, stiffness and bone problems
Some people taking combination therapy for HIV develop a condition called *osteonecrosis* (bone infarction). With this condition, parts of the bone tissue are permanently damaged because of reduced blood supply to the bone. People may be more likely to develop this condition:
- if they have been taking combination therapy for a long time

- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune system is very weak
- if they are overweight.

Signs of osteonecrosis include:
- stiffness in the joints
- aches and pains in the joints (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:
→ **Tell your physician.**

Weight, blood lipid and blood sugar effects
During HIV therapy, there may be an increase in weight and in levels of blood lipids and glucose. These effects are partly linked to restored health and lifestyle, and sometimes to the HIV medicines themselves. Your physician will test for these changes.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the physician.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not discard medicines via wastewater or household waste. Consult with the pharmacist on how to throw away medicines that are not in use. These steps will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains – microcrystalline cellulose, mannitol, sodium starch glycolate (Type A), povidone (K29/32), sodium stearyl fumarate, magnesium stearate, hypromellose (E464), titanium dioxide (E171), macrogol (E1521).

What the medicine looks like and the contents of the package

Dovato film-coated tablets are oval, biconvex, white tablets debossed with the code “SV 137” on one side.
The tablets are provided in bottles closed with a child-resistant cap.
Each bottle contains 30 tablets.
Instructions for opening the bottle: To remove the cap, simultaneously press down and turn left (counterclockwise).
Instructions for closing the bottle: Place the cap on the opening of the bottle and turn right (clockwise) until fully closed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: ViiV Healthcare UK Limited, London, UK.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 165-26-36147

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