# SUMMARY OF PRODUCT CHARACTERISTICS
## DOVATO (Dolutegravir 50 mg / Lamivudine 300 mg Film-Coated Tablets)

## 1. NAME OF THE MEDICINAL PRODUCT

DOVATO (Dolutegravir 50 mg / Lamivudine 300 mg Film-Coated Tablets)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains dolutegravir sodium equivalent to dolutegravir 50 mg and lamivudine 300 mg.

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Film-coated tablet.

Oval, white to off-white, biconvex film-coated tablet debossed with "SV 137" on one face.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

DOVATO is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents from 12 years of age weighing at least 40 kg, who have no known or suspected resistance to either antiretroviral component.

### 4.2 Posology and method of administration

Therapy should be initiated by a physician experienced in the management of HIV infection. One tablet once daily. DOVATO can be taken with or without food. DOVATO is a fixed-dose tablet and should not be prescribed for patients requiring dose adjustments such as those with creatinine clearance <30 mL/min. Not recommended for children <12 years of age or weighing <40 kg. For patients with integrase inhibitor resistance, DOVATO is not recommended.

**Special populations**

Elderly: No evidence that elderly patients require a different dose; consider greater frequency of decreased hepatic/renal function and concomitant medications. Renal impairment: No dolutegravir dose adjustment required; lamivudine dose adjustment required if CrCl <50 mL/min — DOVATO is not recommended for patients with CrCl <30 mL/min. Hepatic impairment: No dose adjustment in mild or moderate hepatic impairment (Child-Pugh A or B). No data in severe hepatic impairment (Child-Pugh C) — use with caution.

**Method of administration**

Oral. May be taken with or without food.

### 4.3 Contraindications

- Hypersensitivity to dolutegravir, lamivudine or to any of the excipients listed in section 6.1.
- Concomitant use with medicinal products with narrow therapeutic windows that are substrates of organic cation transporter 2 (OCT2), including but not limited to dofetilide, pilsicainide or fampridine (dalfampridine).

### 4.4 Special warnings and precautions for use

**Hypersensitivity reactions**

Hypersensitivity reactions — characterised by rash, constitutional findings and sometimes organ dysfunction including liver injury — have been reported with integrase inhibitors including dolutegravir. Discontinue DOVATO immediately if signs or symptoms develop. Monitor clinical status including liver aminotransferases. Do not restart DOVATO or other suspect agents after hypersensitivity develops.

**Neural tube defects**

Neural tube defects have been observed in infants born to women exposed to dolutegravir-containing regimens at the time of conception. The benefit/risk of dolutegravir should be considered in women of childbearing potential who are pregnant or planning pregnancy. Women of childbearing potential should use effective contraception. Prescribers should ensure patients have accurate information about the risks. If a patient

becomes pregnant while taking DOVATO, switch to a regimen not containing dolutegravir during the first trimester, if an alternative is available.

**Immune reconstitution inflammatory syndrome (IRIS)**

IRIS may occur and has been associated with the initiation of any antiretroviral therapy. Autoimmune disorders (e.g. Graves' disease) have also been reported; onset can be many months after initiation of treatment.

**Weight and metabolic parameters**

Increases in weight and in levels of blood lipids and blood glucose may occur during antiretroviral therapy. These changes may in part be linked to disease control and lifestyle. Consider lipid monitoring.

**Lactic acidosis and hepatomegaly**

Lactic acidosis and severe hepatomegaly with steatosis — including fatal cases — have been reported with the use of nucleoside analogues. DOVATO should be discontinued if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity occur.

**Hepatic disease**

For patients with chronic hepatitis B or C treated with antiretrovirals, risk of hepatic decompensation and hepatic failure is higher. Closely monitor hepatic function.

**Interactions with other medicinal products**

Several drugs affect the pharmacokinetics of dolutegravir or lamivudine — see section 4.5. In particular, dolutegravir increases plasma concentrations of metformin; consider dose adjustment of metformin when starting or stopping DOVATO. Dolutegravir increases serum creatinine (by inhibiting renal OCT2 tubular secretion) without affecting actual GFR; consider this when monitoring renal function.

## 4.5 Interaction with other medicinal products and other forms of interaction

Dolutegravir inhibits renal OCT2 and MATE1, increasing plasma concentrations of substrates (dofetilide, pilsicainide, fampridine, metformin). Co-administration with OCT2/MATE1 substrates with narrow therapeutic windows is contraindicated. Polyvalent cation-containing antacids/laxatives/supplements: significantly decrease dolutegravir exposure — take DOVATO 2 hours before or 6 hours after. Rifampicin, carbamazepine, phenytoin, phenobarbital, St. John's Wort: reduce dolutegravir exposure. Etravirine (without darunavir/ritonavir or lopinavir/ritonavir): reduces dolutegravir levels. Tipranavir/ritonavir: reduces dolutegravir levels. Efavirenz, fosamprenavir/ritonavir, rifapentine (all reduce dolutegravir): may require dose increase of dolutegravir. Lamivudine: sorbitol-containing solutions reduce lamivudine absorption; antiviral agents for hepatitis C (sofosbuvir, simeprevir) — no dose adjustment needed.

## 4.6 Fertility, pregnancy and lactation

**Pregnancy**

Neural tube defects have been observed in infants whose mothers were exposed to dolutegravir at the time of conception (see section 4.4). DOVATO should be used during pregnancy only if the benefit clearly outweighs the risk. A switch away from dolutegravir should be considered during the first trimester if a suitable alternative is available. Lamivudine is used during pregnancy — including in combination regimens — without evidence of teratogenicity.

**Breast-feeding**

HIV-infected women should not breast-feed to avoid transmission of HIV to infants. Both dolutegravir and lamivudine are excreted into human breast milk. Breast-feeding should be discontinued during treatment.

**Fertility**

No effects on fertility have been observed in clinical use with dolutegravir or lamivudine.

## 4.7 Effects on ability to drive and use machines

DOVATO has a minor influence on the ability to drive and use machines due to dizziness reported as an adverse reaction.

## 4.8 Undesirable effects

The most common adverse reactions with DOVATO (≥2%) are insomnia and headache. Less commonly reported events include hypersensitivity reactions, nausea, diarrhoea, rash, fatigue, dizziness, and abnormal dreams. Immune reconstitution syndrome, weight gain, and laboratory abnormalities (elevated liver enzymes, elevated creatine phosphokinase, elevated blood bilirubin, decreased neutrophil count) have been reported. Lactic acidosis (a rare but serious risk with lamivudine) must be considered.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

### 4.9 Overdose

Limited data on overdose. Treatment is symptomatic and supportive. Monitor vital signs, blood counts, liver enzymes and renal function. Haemodialysis removes lamivudine from the systemic circulation.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antivirals for systemic use; antivirals for treatment of HIV infections, combinations. ATC code: J05AR.

Dolutegravir is an integrase strand transfer inhibitor (INSTI) that binds to the active site of HIV integrase and blocks the strand transfer step of retroviral DNA integration. Lamivudine is a nucleoside reverse transcriptase inhibitor (NRTI) that acts as a chain terminator following phosphorylation to lamivudine-5'-triphosphate. The two components have complementary and synergistic antiviral activity against HIV-1. In the GEMINI-1 and GEMINI-2 studies (Phase 3, treatment-naïve patients, virological suppression maintained through 96 weeks), dolutegravir plus lamivudine was non-inferior to dolutegravir plus tenofovir/emtricitabine.

### 5.2 Pharmacokinetic properties

Dolutegravir: Orally bioavailable; absolute bioavailability not established. Extensively protein-bound (>99%). Metabolised primarily by CYP3A (minor) and UGT1A1 (major). Terminal half-life approximately 14 hours. Excreted mainly via faeces (53%) and urine (31%) as metabolites. Lamivudine: Rapidly absorbed after oral administration; bioavailability approximately 86%. Primarily eliminated unchanged by the kidney via active organic cationic secretion; half-life 18–19 hours intracellularly (as lamivudine-TP).

### 5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity for both dolutegravir and lamivudine.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet core: Microcrystalline cellulose, sodium starch glycolate, mannitol (E421), povidone K29/32, sodium stearyl fumarate. Tablet coating: Hypromellose (E464), macrogol, titanium dioxide (E171).

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Do not store above 30°C

### 6.5 Nature and contents of container

Opaque, white HDPE bottle with polypropylene child-resistant closure. Each bottle contains 30 film-coated tablets. One bottle per pack.

### 6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

**GlaxoSmithKline (Kenya) Limited**

(Member of the GSK group of companies)
Manufactured by: GlaxoSmithKline LLC, 1011 North Arendell Avenue, Zebulon, North Carolina 27597, USA.

## 8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD8497/17135

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

23.03.2026

## 10. DATE OF REVISION OF THE TEXT

23.03.2026