Dovato
dolutegravir/lamivudine

WORKING ON BEHALF OF
ViiV HEALTHCARE IN HIV

צוות רפואי נכבד

ספטמבר 2020

חברת gsk (ישראל)
שמחה לעדכן על התחלת שיווק תכשיר חדש

Dovato
dolutegravir/lamivudine
Film Coated Tablets

2 תרופות בלבד, בכדור אחד[1]

חומרים פעילים

Dolutegravir (as sodium) – 50mg
Lamivudine – 300 mg

התכשיר נרשם בישראל להתוויה הבאה

Dovato is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighting at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine and viral load ≤500,000 c/mL.

מינון

The recommended dose of Dovato in adults and adolescents is one tablet once daily (Per OS).
Dovato can be taken with or without food.
A separate preparation of dolutegravir is available where a dose adjustment is indicated due to drug-drug interactions (see section 4.4, 4.5).
In these cases the physician should refer to the individual product information for dolutegravir.[1]

יצרן

Glaxo Welcome S.A. Spain

למידע מלא יש לעיין בעלונים לרופא ולצרכן המאושרים על ידי משרד הבריאות.
העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות.
כמו כן, ניתן לקבלם מודפסים ע"י פניה לבעל הרישום, חברת גלקסוסמיתקליין (ישראל) בע"מ
בטל': 03-9297100

בברכה,

דר' ורדה אשד, מנהלת רפואית
אורית כרם, מנהלת מוצרים

Full PI attached to mail

1.DOVATO MOH approved Prescribing Information

DOVATO (Dolutegravir 50mg/ Lamivudine 300mg)
Main Safety Information (09/2020)

For full information see MOH approved prescribing information

Therapeutic indications: Dovato is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighting at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine and viral load ≤500,000 c/mL.
Special warnings and precautions for use:
Hypersensitivity reactions if suspected Dovato should be discontinued immediately. Immune reactivation syndrome, osteonecrosis, increased weight, lipids, glucose. Dovato should be used with caution in severe hepatic impairment.
Monitor LFTs in Hepatitis B/C co-infection and additional antiviral is needed for HBV. Mitochondrial dysfunction following exposure in utero. Use with Mg/Al-containing antacids and Ca/Fe supplements requires dosage separation.
Dose adjustment of metformin should be considered when starting and stopping co-administration with Dovato.
Dovato should not co-administered with polyvalent cation-containing antacids at the same time requires dosage separation.
The combination of Dovato with cladribine is not recommended.
Dovato is not recommended for use in patients with a creatinine clearance < 50 ml/min.
Pregnancy: The safety and efficacy of a dual regimen has not been studied in pregnancy. Women Of Childbearing Potential should undergo pregnancy testing before initiation of Dovato. WOCBP should use effective contraception throughout treatment.
Contraindications: Hypersensitivity to active substances or to any of the excipients.
Co-administration with medical products with narrow therapeutic windows, that are substrates of OCT2, including but not limited to fampridine
Adverse events: Very common (≥1/10) reported adverse reactions: Headache, nausea, diarrhea. Common (≥1/100 to <1/10): Insomnia, depression, anxiety, dizziness, somnolence, fatigue, flatulence.Trade marks are owned by or licensed to the ViiV Healthcare group of companies.

Important GSK Information
GlaxoSmithKline. 25 Basel street, P.O. Box 3345, Petach-Tikva 4951038 Israel, Tel: 03-9297100.
Medical information service: il.medinfo@gsk.com
Adverse events reporting service: il.safety@gsk.com, Tel: 03-9297100

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