



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 218644 TRIUMEQ dolutegravir (as sodium) 50 mg/abacavir (as sulfate) 600 mg/lamivudine 300mg tablet bottles

ARTG entry for Medicine Registered
Sponsor ViiV Healthcare Pty Ltd
Postal Address PO Box 18095, MELBOURNE CITY MC, VIC, 8001
 Australia
ARTG Start Date 14/01/2015
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. TRIUMEQ dolutegravir (as sodium) 50 mg/abacavir (as sulfate) 600 mg/lamivudine 300mg tablet bottle

Product Type	Single Medicine Product	Effective date	13/12/2018
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Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

TRIUMEQ is indicated for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age who are antiretroviral treatment-naïve or are infected with HIV without documented or clinically suspected resistance to any of the three antiretroviral agents (dolutegravir, abacavir or lamivudine) in TRIUMEQ.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	36 Months	Store below 30 degrees Celsius	Child resistant closure	Keep Container Tightly Closed/Airtight Store in Original Container Protect from Moisture

Pack Size/Poison information

Pack Size 30 tablets	Poison Schedule (S4) Prescription Only Medicine
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Components

1. TRIUMEQ dolutegravir (as sodium) 50 mg/abacavir (as sulfate) 600 mg/lamivudine 300mg tablet bottle

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification Purple, biconvex, film coated oval tablets (approximately 22 x 11 mm), debossed with "572 Tri" on one face.

Active Ingredients

Abacavir sulfate	702 mg
Dolutegravir	50 mg
Lamivudine	300 mg

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