Public Summary

Summary for ARTG Entry: 99090 KIVEXA abacavir 600mg (as sulfate) and lamivudine 300mg tablet blister pack

ARTG entry for	Medicine Registered
Sponsor	ViiV Healthcare Pty Ltd
Postal Address	PO Box 18095, MELBOURNE CITY MC, VIC, 8001 Australia
ARTG Start Date	24/03/2005
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 . KIVEXA abacavir 600 mg (as sulfate) and lamivudine 300 mg tablet blister pack

Product Type Single Medicine Product **Effective Date** 6/06/2019

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

KIVEXA tablets are a combination of two nucleoside analogues (abacavir and lamivudine). KIVEXA is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PVDC/Al	3 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
30 Tablets	(S4) Prescription Only Medicine

Components

1 . KIVEXA abacavir 600 mg (as sulfate) and lamivudine 300 mg tablet blister pack

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Orange, film-coated, modified capsule shaped tablets, debossed with GS FC2 on one side.

Active Ingredients

abacavir sulfate	**702 mg**
Equivalent: abacavir	600 mg
lamivudine	**300 mg**

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Other Ingredients (Excipients)

hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
polysorbate 80
sodium starch glycollate
sunset yellow FCF
titanium dioxide