Public Summary

Summary for ARTG Entry:	166483	MAVENCLAD cladribine 10mg tablet blister pack

ARTG entry for	Medicine Registered
Sponsor	Merck Healthcare Pty Ltd
Postal Address	PO Box 125, North Ryde BC, NSW, 1670 Australia
ARTG Start Date	9/09/2010
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 . MAVENCLAD cladribine 10mg tablet blister pack

Product Type	Single Medicine Product	**Effective Date**	18/07/2022

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

MAVENCLAD is indicated for the treatment of relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability.,Following completion of the 2 treatment courses, no further cladribine treatment is required in years 3 and 4. Re-initiation of therapy after year 4 has not been studied.

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	Al/Al	48 Months	Store below 30 degrees Celsius	Child resistant closure	Protect from Moisture

Pack Size/Poison information

Pack Size	Poison Schedule
1 tablet	(S4) Prescription Only Medicine
7 tablets	(S4) Prescription Only Medicine
6 tablets	(S4) Prescription Only Medicine
9 tablets	(S4) Prescription Only Medicine
4 tablets	(S4) Prescription Only Medicine
5 tablets	(S4) Prescription Only Medicine
8 tablets	(S4) Prescription Only Medicine
10 tablets	(S4) Prescription Only Medicine

Components

1 .

Dosage Form	Tablet, uncoated

Route of Administration	Oral
Visual Identification	White, round, biconvex tablets engraved "C" on one side, "10" on other

Active Ingredients	
cladribine	**10 mg**

Other Ingredients (Excipients)
hydroxypropylbetadex
magnesium stearate
sorbitol

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