Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 387621 TECVAYLI teclistamab 10mg/mL solution for injection vial

ARTG entry for	Medicine Registered (Provisional)
Sponsor	Janssen-Cilag Pty Ltd
Postal Address	Locked Bag 2070, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date	14/06/2023
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Medicine under additional monitoring

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 . TECVAYLI teclistamab 10mg/mL solution for injection vial

Product Type Single Medicine Product **Effective Date** 5/09/2023 10:03:33 AM

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

Provisionally Registered Indications

TECVAYLI as monotherapy has provisional approval in Australia and is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.,The decision to approve this indication has been made on the basis of the overall response rate in a single arm study. Continued approval of this indication depends on verification and description of benefit in confirmatory trials.

Provisionally Registered Conditions

Provisional registration with conditions as specified in the letter dated 02 June 2023 from CESC PMAB advising of approval for the registration of the goods (PM-2022-01541-1-6) D23-5434818

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	18 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Do not Freeze Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
1	(S4) Prescription Only Medicine

Public Summary

Components

1 . TECVAYLI teclistamab 10mg/mL solution for injection vial

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	Colourless to light yellow preservative-free solution for injection in a vial.

Active Ingredients

teclistamab	**30 mg**

Other Ingredients (Excipients)

disodium edetate
glacial acetic acid
polysorbate 20
sodium acetate trihydrate
sucrose
water for injections

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