



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	334511	REBLOZYL luspatercept 75 mg powder for injection vial
ARTG entry for	Medicine Registered	
Sponsor	Celgene Pty Ltd	
Postal Address	Level 15 / 60 City Road, Southbank, VIC, 3006 Australia	
ARTG Start Date	30/08/2021	
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 . REBLOZYL luspatercept 75 mg powder for injection vial

Product Type	Single Medicine Product	Effective Date	30/08/2021
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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

REBLOZYL is indicated for the treatment of adult patients with transfusion-dependent anaemia (requiring 2 or more RBC units over 8 weeks) due to very low, low and intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS).,REBLOZYL is indicated for the treatment of adult patients with transfusion-dependent anaemia associated with beta thalassaemia.,Limitation of Use,REBLOZYL is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anaemia.

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	3 Years	Store at 2 to 8 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
1 vial	(S4) Prescription Only Medicine

Components

1 . REBLOZYL luspatercept 75 mg powder for injection vial

Dosage Form	Injection, powder for
Route of Administration	Subcutaneous
Visual Identification	White to off-white powder, free of visible foreign matter

Active Ingredients

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luspatercept

75 mg

Other Ingredients (Excipients)

citric acid monohydrate

hydrochloric acid

polysorbate 80

sodium citrate dihydrate

sodium hydroxide

sucrose

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