




**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	375984	SKYRIZI risankizumab 600 mg/10 mL concentrate solution for intravenous infusion vial
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Abbvie Pty Ltd	
<b>Postal Address</b>	Locked Bag 5029, BOTANY, NSW, 1455 Australia	
<b>ARTG Start Date</b>	5/10/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . SKYRIZI risankizumab 600 mg/10 mL concentrate solution for intravenous infusion vial

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	9/02/2024
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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

Crohn's Disease, SKYRIZI is indicated for the treatment of moderate to severe Crohn's disease in adult patients, who have an inadequate response, a lost response, an intolerance or a contra-indication to either conventional or biologic therapy.

#### 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	24 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light Do not Freeze Refrigerate

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
1 x Vial	(S4) Prescription Only Medicine

#### Components

##### 1 . SKYRIZI risankizumab 600 mg/10 mL concentrate solution for intravenous infusion vial

<b>Dosage Form</b>	Injection, intravenous infusion
<b>Route of Administration</b>	Intravenous Infusion
<b>Visual Identification</b>	600 mg/10 mL Vial: The solution is colourless to slightly yellow and clear to slightly opalescent. The solution may contain a few translucent to white product-related particles.

#### Active Ingredients

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Risankizumab

600 mg

**Other Ingredients (Excipients)**

glacial acetic acid

polysorbate 20

sodium acetate trihydrate

trehalose dihydrate

water for injections

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