



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	366760	FILPEGLA pegfilgrastim 6 mg/0.6 mL solution for injection syringe
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Cipla Australia Pty Ltd	
<b>Postal Address</b>	Level 1 / 132-136 Albert Road, SOUTH MELBOURNE, VIC, 3205 Australia	
<b>ARTG Start Date</b>	19/08/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . FILPEGLA pegfilgrastim 6 mg/0.6 mL solution for injection syringe

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/08/2022
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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

FILPEGLA is indicated for the treatment of cancer patients following chemotherapy, to decrease the duration of severe neutropenia and so reduce the incidence of infection, as manifested by febrile neutropenia.

#### Warnings

See Product Information and Consumer Medicine Information for this product

#### Additional Product information

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass Type I Clear	36 Months	Store at 2 to 8 degrees Celsius	Not recorded	Protect from Light Do not Shake Do not Freeze Refrigerate

#### Pack Size/Poison information

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

#### Components

##### 1 . FILPEGLA pegfilgrastim 6 mg/0.6 mL solution for injection syringe

<b>Dosage Form</b>	Injection, solution
<b>Route of Administration</b>	Subcutaneous
<b>Visual Identification</b>	Is a sterile, clear and colourless preservative-free solution for injection for subcutaneous (SC) administration

#### Active Ingredients

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**Pegfilgrastim**

**6 mg**

**Other Ingredients (Excipients)**

glacial acetic acid  
polysorbate 20  
sodium hydroxide  
sorbitol  
water for injections

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