



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

## Public Summary

|                                |  |   |
|--------------------------------|--|---|
| <b>Summary for ARTG Entry:</b> | 370765                                       | SUNITINIB MSN sunitinib (as malate) 12.5 mg hard capsule bottle |
| <b>ARTG entry for</b>          | Medicine Registered                          |   |
| <b>Sponsor</b>                 | Accelagen Pty Ltd                            |   |
| <b>Postal Address</b>          | PO Box 249, Kew East, VIC, 3102<br>Australia |   |
| <b>ARTG Start Date</b>         | 22/07/2022                                   |   |
| <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 . SUNITINIB MSN sunitinib (as malate) 12.5 mg hard capsule bottle

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 29/03/2023 |
|---------------------|-------------------------|-----------------------|------------|

**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**  
Sunitinib MSN is indicated for; treatment of advanced renal cell carcinoma (RCC), treatment of gastrointestinal stromal tumour (GIST) after failure of imatinib mesilate treatment due to resistance or intolerance, treatment of unresectable, well-differentiated pancreatic neuroendocrine tumours (pancreatic NET)

**Warnings**  
See Product Information and Consumer Medicine Information for this product

**Additional Product information**

#### Container information

| Type   | Material | Life Time | Temperature                    | Closure      | Conditions   |
|--------|----------|-----------|--------------------------------|--------------|--------------|
| Bottle | HDPE     | 24 Months | Store below 25 degrees Celsius | Not recorded | Not recorded |

#### Pack Size/Poison information

| Pack Size        | Poison Schedule                 |
|------------------|---------------------------------|
| 30 hard capsules | (S4) Prescription Only Medicine |
| 28 hard capsules | (S4) Prescription Only Medicine |

#### Components

##### 1 . SUNITINIB MSN sunitinib (as malate) 12.5 mg hard capsule bottle

|                                |  |
|--------------------------------|--|
| <b>Dosage Form</b>             | Capsule, hard  |
| <b>Route of Administration</b> | Oral   |
| <b>Visual Identification</b>   | Hard gelatin capsules with orange opaque body imprinted with "6" and orange opaque cap imprinted with "MS" in white ink, free from physical defects. |

|                           |                  |
|---------------------------|------------------|
| <b>Active Ingredients</b> |                  |
| <b>sunitinib malate</b>   | <b>16.706 mg</b> |
| Equivalent: sunitinib     | 12.5 mg          |

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**Other Ingredients (Excipients)**

ammonia  
butan-1-ol  
croscarmellose sodium  
ethanol absolute  
Gelatin  
iron oxide red  
isopropyl alcohol  
magnesium stearate  
mannitol  
potassium hydroxide  
pregelatinised maize starch  
propylene glycol  
purified water  
Shellac  
titanium dioxide

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