



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

## Public Summary

<b>Summary for ARTG Entry:</b>	370768	SUNITINIB MSN sunitinib (as malate) 50 mg hard capsule blister pack
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Accelagen Pty Ltd	
<b>Postal Address</b>	PO Box 249, Kew East, VIC, 3102 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) 50 mg hard capsule blister pack

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

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
Blister Pack	PVC/PCTFE (Aclar)/Al	24 Months	Store below 25 degrees Celsius	Not recorded	Not recorded

#### Pack Size/Poison information

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

#### Components

##### 1 . SUNITINIB MSN sunitinib (as malate) 50 mg hard capsule blister pack

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	Hard gelatin capsules with caramel opaque body imprinted with "9" and caramel opaque cap imprinted with "MS" in white ink, free from physical defects.

#### Active Ingredients

<b>sunitinib malate</b>	<b>66.824 mg</b>
Equivalent: sunitinib	50 mg

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**Other Ingredients (Excipients)**

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

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