



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370769	SUNITINIB MSN sunitinib (as malate) 12.5 mg hard capsule blister pack
ARTG entry for	Medicine Registered	
Sponsor	Accelagen Pty Ltd	
Postal Address	PO Box 249, Kew East, VIC, 3102 Australia	
ARTG Start Date	22/07/2022	
Product Category	Medicine	
Status	Active	
Approval Area	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 blister pack

Product Type	Single Medicine Product	Effective Date	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
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 blister pack

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

Active Ingredients	
sunitinib malate	16.706 mg
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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