



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370766	SUNITINIB MSN sunitinib (as malate) 25 mg hard capsule bottle
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) 25 mg hard capsule bottle

Product Type	Single Medicine Product	Effective Date	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
28 hard capsules	(S4) Prescription Only Medicine
30 hard capsules	(S4) Prescription Only Medicine

Components

1 . SUNITINIB MSN sunitinib (as malate) 25 mg hard capsule bottle

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	Hard gelatin capsules with orange opaque body imprinted with "7" and caramel opaque cap imprinted with "MS" in white ink, free from physical defects.

Active Ingredients

sunitinib malate	33.412 mg
Equivalent: sunitinib	25 mg



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary