



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370770	SUNITINIB MSN sunitinib (as malate) 37.5 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) 37.5 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
28 hard capsules	(S4) Prescription Only Medicine
30 hard capsules	(S4) Prescription Only Medicine

Components

1 . SUNITINIB MSN sunitinib (as malate) 37.5 mg hard capsule blister pack

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	Hard gelatin capsules with yellow opaque body imprinted with "8" and yellow opaque cap imprinted with "MS" in black ink, free from physical defects.

Active Ingredients

sunitinib malate	50.118 mg
Equivalent: sunitinib	37.5 mg



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Other Ingredients (Excipients)

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

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