



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 285900 GLIVANIB imatinib (as mesilate) 400 mg capsules blister pack

ARTG entry for Medicine Registered
Sponsor Juno Pharmaceuticals Pty Ltd
Postal Address Level 2 6 Bond Street, South Yarra, VIC, 3141
 Australia
ARTG Start Date 8/05/2017
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. GLIVANIB imatinib (as mesilate) 400 mg capsules blister pack

Product Type	Single Medicine Product	Effective date	11/09/2017
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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

- treatment of patients with chronic myeloid leukaemia (CML)
- treatment of adult patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy
- treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy
- treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements, where conventional therapies have failed
- treatment of adult patients with aggressive systemic mastocytosis (ASM), where conventional therapies have failed
- treatment of adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL)
- adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).

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/PE/PVDC/Al	24 Months	Store below 30 degrees Celsius	Not recorded	Protect from Moisture

Pack Size/Poison information

Pack Size	Poison Schedule
30	(S4) Prescription Only Medicine
24	(S4) Prescription Only Medicine
120	(S4) Prescription Only Medicine
180	(S4) Prescription Only Medicine
48	(S4) Prescription Only Medicine
96	(S4) Prescription Only Medicine

Components

1. GLIVANIB imatinib (as mesilate) 400 mg capsules blister pack

Dosage Form Capsule

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Route of Administration

Oral

Visual Identification

Light yellow granules filled in size 00EL hard gelatin capsules with brown cap and brown body.

Active Ingredients

imatinib mesilate

478 mg

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