



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 285899 GLIVANIB imatinib (as mesilate) 100 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) 100 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
96	(S4) Prescription Only Medicine
60	(S4) Prescription Only Medicine
120	(S4) Prescription Only Medicine
24	(S4) Prescription Only Medicine
48	(S4) Prescription Only Medicine
180	(S4) Prescription Only Medicine

**Components**

**1. GLIVANIB imatinib (as mesilate) 100 mg capsules blister pack**

**Dosage Form** Capsule

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**Route of Administration**

Oral

**Visual Identification**

Light yellow granules filled in size 3 hard gelatin capsule with brown cap and white body.

**Active Ingredients**

imatinib mesilate

**119.5 mg**

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