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# Lupin in alliance with Natco receives FDA approval for Imatinib Mesylate Tablets

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**Imatinib Mesylate Tablets is the generic version of Novartis' Gleevec® Tablets**


Lupin and Natco Pharma has announced the final ANDA approval for Imatinib Mesylate Tablets, 100 mg (base) and 400 mg (base) from the United States Food and Drug Administration (FDA) to market a generic version of Novartis Pharmaceuticals Corporation's (Novartis) Gleevec® Tablets, 100mg and 400mg.

Lupin and Natco's Imatinib Mesylate Tablets, 100 mg (base) and 400 mg (base) is the generic version of Novartis' Gleevec® Tablets, 100 mg and 400 mg. It is indicated for the treatment of :

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy.
- Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).
- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements as determined with an FDA-approved test.
- Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation as determined with an FDA-approved test or with c-Kit mutational status unknown.
- Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFR? fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFR? fusion kinase negative or unknown.
- Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).

Imatinib Mesylate Tablets, 100 mg (base) and 400 mg (base) had annual sales of approximately USD 655 mn in the US (IQVIA MAT December 2018).