

Imkeldi® (imatinib) Oral Solution

Fact Sheet



IMKELDI® BENEFITS

- IMKELDI is an advanced liquid formulation of imatinib designed to provide dosing accuracy.
- IMKELDI provides precise dosing based on body surface area at 16 mg dose increments for children without the need for compounding.
- IMKELDI provides precise dosing options from 100 to 800 mg for adults.
- IMKELDI provides a strawberry-flavored palatable alternative to imatinib.
- IMKELDI is easy for patients to swallow.
- Convenient storage and administration
 - Maintains a 30-day shelf life after opening
 - Does not require refrigeration: Store at room temperature between 68°F to 77°F.
 - 80 mg/mL in a 140 mL bottle

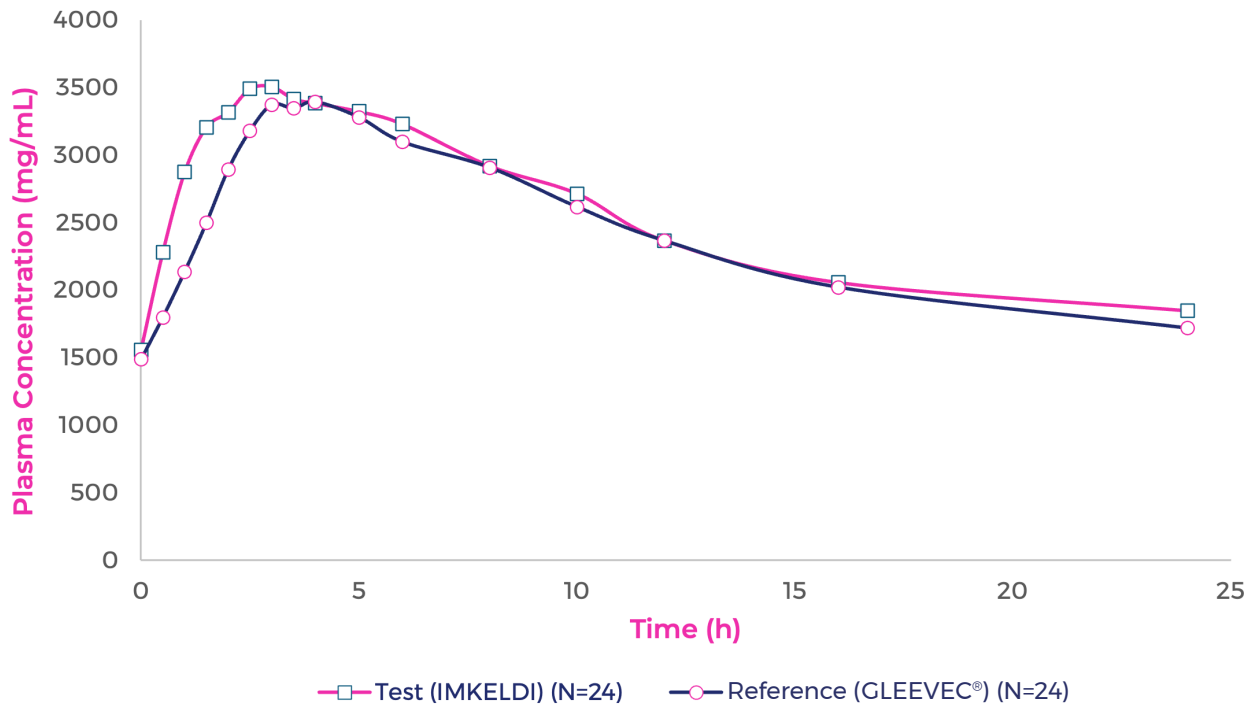
INDICATIONS

IMKELDI is a kinase inhibitor 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).
- Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy.
- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements.
- Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown.
- Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRa fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown.
- Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).
- Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST).
- Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST.

IMKELDI is Bioequivalent to GLEEVEC®

IMKELDI is labeled with the same safety and efficacy profile as imatinib.



Graphical representation of relative bioavailability of GLEEVEC® tablet concentrations compared to IMKELDI concentrations.

- A study to compare and evaluate the multiple-dose oral bioavailability of Imatinib Mesylate Oral Solution (400 mg/5 mL) with GLEEVEC® (Imatinib mesylate) tablet (400 mg) in adult human patients with Chronic Myeloid Leukemia and/or Gastrointestinal Stromal Tumor under fed condition.¹
- Assessment of bioequivalence was based upon 90% confidence intervals (CI) for the ratio of the population geometric least square mean (T/R) for AUC_{0-t} and $C_{max,ss}$. In accordance with the study protocol, data from 32 subjects who completed the study were used for pharmacokinetic calculation. However, total 8 subject did not achieve steady state. Hence, statistical analysis was performed on 24 subjects.²

1. GLEEVEC® (Imatinib mesylate) Tablets 400 mg are a product of Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936.

2. Data on File, Shorla Oncology, 2018.

For full Prescribing Information, please visit

shorlaoncology.com/imkeldi.

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Pediatric Dosing Recommendations

IMKELDI delivers consistent, precise dosing for pediatric patients based on their body surface area (BSA) at 16 mg dose increments without the need for compounding. IMKELDI is an advanced liquid formulation of imatinib designed to provide dosing accuracy. IMKELDI has a concentration of 80 mg/mL which allows for easy dose calculation.

Indication	Imatinib Dose (mg)
Pediatrics with Ph+ CML CP	340 mg/m ² /day
Pediatrics with Ph+ ALL	340 mg/m ² /day

Doses shown are intended for illustrative purposes only and are not a replacement for clinical judgment.

Body Surface Area (m ²)	Imatinib Dose (mg)	IMKELDI Dose (80 mg/mL)
0.75 m ²	340 mg/m ² /day = 255 mg/day	3.2 mL
1.04 m ²	340 mg/m ² /day = 354 mg/day	4.4 mL
1.32 m ²	340 mg/m ² /day = 449 mg/day	5.6 mL

Adult Dosing Recommendations

IMKELDI has a concentration of 80 mg/mL, which allows for easy dose calculation. A 400 mg dose of IMKELDI is 5 mL.



All doses of IMKELDI should be taken with a meal and a large glass of water.

Adults











Indications	IMKELDI Dose (80 mg/mL)
Adults with Ph+ CML CP	400 mg/day
Adults with Ph+ CML AP or BC	600 mg/day
Adults with Ph+ ALL	600 mg/day
Adults with MDS/MPD	400 mg/day
Adults with ASM	100 mg/day or 400 mg/day
Adults with HES/CEL	100 mg/day or 400 mg/day
Adults with DFSP	800 mg/day
Adults with metastatic and/or unresectable GIST	400 mg/day
Adjuvant treatment of adults with GIST	400 mg/day

Patients with Hepatic Impairments

Indications	IMKELDI Dose (80 mg/mL)
Patients with mild to moderate hepatic impairment	400 mg/day
Patients with severe hepatic impairment	300 mg/day

Tablet to Liquid Imatinib Dosing Conversion

IMKELDI provides precise dosing options from 100 mg to 800 mg for adults without the need for compounding. IMKELDI has a concentration of 80 mg/mL which allows for easy dose calculation.

Imatinib Dose (mg)	Imatinib Tablets (mg)	IMKELDI Dose (80 mg/mL)
100 mg	 1 x 100 mg	 1.25 mL
300 mg	 3 x 100 mg	 3.75 mL
400 mg	 1 x 400 mg	 5 mL
600 mg	 2 x 100 mg + 1 x 400 mg	 7.5 mL
800 mg	 2 x 400 mg	 2 x 5 mL

Bottle Adapter and Dosing Syringe

The dispensing pharmacy needs to provide a compatible adapter and oral syringe for administration of IMKELDI.

Item Name	Manufacturer	Item Code
Comar [®] Press-in Bottle Adapter, 28 mm	Comar	#17284

This same adapter is also available from Health Care Logistics Inc. (HCL[®] by Comar[®]) – Adapter (28mm, BN: 05242023)

Compatible Oral Syringes

3 mL syringes:

Item Name	Volume	Manufacturer	Item Code	Graduation
Monoject [™]	3 mL	Cardinal	#120206	0.1 mL
Exacta-Med [®]	3 mL	Baxter	#464101	0.1 mL
HCL [®] by Comar [®]	3 mL	Comar	#16031W	0.1 mL

10 mL syringes:

Item Name	Volume	Manufacturer	Item Code	Graduation
Monoject [™]	10 mL	Cardinal	#53842	0.2 mL
CareTip	10 mL	MED Alliance Group Inc	#1200586	0.2 mL
HCL [®] by Comar [®]	10 mL	Comar	#16039W	0.2 mL

When dispensing, the pharmacist must provide patient instructions for use and include a sticker showing the product has a 30-day expiration.

Patient Assistance



Shorla is committed to ensuring access to medications for patients in need. For patients with prescription drug coverage, our patient assistance program can help guide patients and caregivers through the reimbursement process and offer patient support services to assist with out-of-pocket costs.

\$15

Copay Support for Commercially Insured Patients

When prescribed, IMKELDI is available for as little as \$15 for commercially insured patients. No cards, coupons, or calls required.

Quick Start Program

Quick Start ensures timely access to treatment to eligible patients with insurance delays.

After 3 business days, eligibility is assessed, and if deemed appropriate, the Quick Start prescription is requested.

The program covers a one-month supply while the initial prescription is being processed.

Patient Assistance Program for Uninsured

Assistance is available for uninsured patients via form on www.shorlaoncology.com/imkeldi or by calling 1-844-9-SHORLA (1-844-974-6752). Shorla Oncology representatives are available to assist you from 8 AM to 5 PM CT, Monday through Friday.

Reimbursement Support

Reimbursement support is available by contacting 1-844-9-SHORLA (1-844-974-6752), where dedicated professionals work to reduce time to fill, improve fulfillment and improve patient experience.

IMKELDI Ordering Information



IMKELDI

- Available by contract for practices that offer in-office dispensing
- Available with GPO discounts
- NDC 81927-201-01

Authorized Distributors

Morris & Dickson	#034968
Cardinal Specialty	#5965512
McKesson Plasma & Biologic	#3006525
McKesson Specialty	#5019210
Cencora - ASD	#10295735
Cencora - Oncology Supply	#10295765

Order Direct

Shorla Oncology representatives are available to assist you from 8 AM to 5 PM CT, Monday through Friday.



CALL

1-844-974-6752, option 2



FAX

414-501-3169



EMAIL

shorlacs@eversana.com

Important Safety Information

INDICATIONS

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Patients with Ph+ CML in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.
- Adult patients with relapsed or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia.
- Pediatric patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia in combination with chemotherapy.
- Adult patients with myelodysplastic/myeloproliferative diseases associated with platelet-derived growth factor receptor gene rearrangements.
- Adult patients with aggressive systemic mastocytosis without the D816V c-Kit mutation or with c-Kit mutational status unknown.
- Adult patients with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who have the FIP1L1-PDGFR α fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and patients with HES and/or CEL who are FIP1L1-PDGFR α fusion kinase negative or unknown.
- Adult patients with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans.
- Patients with Kit-positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST).
- Adjuvant treatment of adult patients following resection of Kit-positive GIST.

WARNING AND PRECAUTIONS

Fluid Retention and Edema: Edema and severe fluid retention have occurred. Weigh patients regularly and manage unexpected rapid weight gain by drug interruption and diuretics.

Hematologic Toxicity: Cytopenias, particularly anemia, neutropenia, and thrombocytopenia, have occurred. Manage with dose reduction, dose interruption, or discontinuation of treatment. Perform complete blood count weekly for the first month, biweekly for the second month, and periodically thereafter.

Congestive Heart Failure and Left Ventricular Dysfunction: Severe congestive heart failure and left ventricular dysfunction have been reported, particularly in patients with comorbidities and risk factors. Monitor and treat patients with cardiac disease or risk factors for cardiac failure.

Hepatotoxicity: Severe hepatotoxicity, including fatalities may occur. Assess liver function before initiation of treatment and monthly thereafter or as clinically indicated. Monitor liver function when combined with chemotherapy known to be associated with liver dysfunction.

Hemorrhage: Grade 3/4 hemorrhage has been reported in clinical studies in patients with newly diagnosed CML and with GIST. GI tumor sites may be the source of GI bleeds in GIST.

Gastrointestinal Disorders: Gastrointestinal perforations, some fatal, have been reported.

Hypereosinophilic Cardiac Toxicity: Cardiogenic shock/left ventricular dysfunction has been associated with the initiation of IMKELDI in patients with conditions associated with high eosinophil levels (e.g., HES, MDS/MPD, and ASM).

Dermatologic Toxicities: Bullous dermatologic reactions (e.g., erythema multiforme and Stevens-Johnson syndrome) have been reported with the use of IMKELDI.

Hypothyroidism: Hypothyroidism has been reported in thyroidectomy patients undergoing levothyroxine replacement. Closely monitor TSH levels in such patients.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception.

Growth Retardation in Children and Adolescents: Growth retardation occurring in children and preadolescents receiving IMKELDI has been reported. Close monitoring of growth in children under IMKELDI treatment is recommended.

Tumor Lysis Syndrome: Close monitoring is recommended.

Impairments Related to Driving and Using Machinery: Motor vehicle accidents have been reported in patients receiving IMKELDI. Caution patients about driving or operating machinery.

Renal Toxicity: A decline in renal function may occur in patients receiving IMKELDI oral solution. Evaluate renal function at baseline and during therapy, with attention to risk factors for renal dysfunction.

Measuring Device: Advise patients to measure IMKELDI with an accurate milliliter measuring device. Inform patients that a household teaspoon is not an accurate measuring device and could lead to overdosage, which can result in serious adverse reactions. Advise patients to ask their pharmacist to recommend an appropriate press-in bottle adapter and oral dispensing syringe and for instructions for measuring the correct dose.

ADVERSE REACTIONS

The most frequently reported adverse reactions ($\geq 30\%$) are edema, nausea, vomiting, muscle cramps, musculoskeletal pain, diarrhea, rash, fatigue, and abdominal pain.

DRUG INTERACTIONS

- CYP3A4 inducers: Avoid or increase IMKELDI dosage if unavoidable.
- CYP3A4 inhibitors: Use caution. Avoid grapefruit juice.
- CYP3A4 substrates: Use caution. Patients who require anticoagulation should receive other anticoagulants instead of warfarin.
- CYP2D6 substrates: Use caution.

USE IN SPECIFIC POPULATIONS

Lactation: Advise not to breastfeed.

IMKELDI and its active metabolite are excreted into human milk. Because of the potential for serious adverse reactions in breastfed children from IMKELDI, advise a lactating woman not to breastfeed during treatment and for 1 month after the last dose.



To report suspected adverse reactions, contact Shorla Oncology at 1-844-9-SHORLA (1-844-974-6752) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click [here](#) for full Prescribing Information.

For more information, please visit shorlaoncology.com/imkeldi.