

 **Imkeldi**  
(imatinib mesylate)  
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

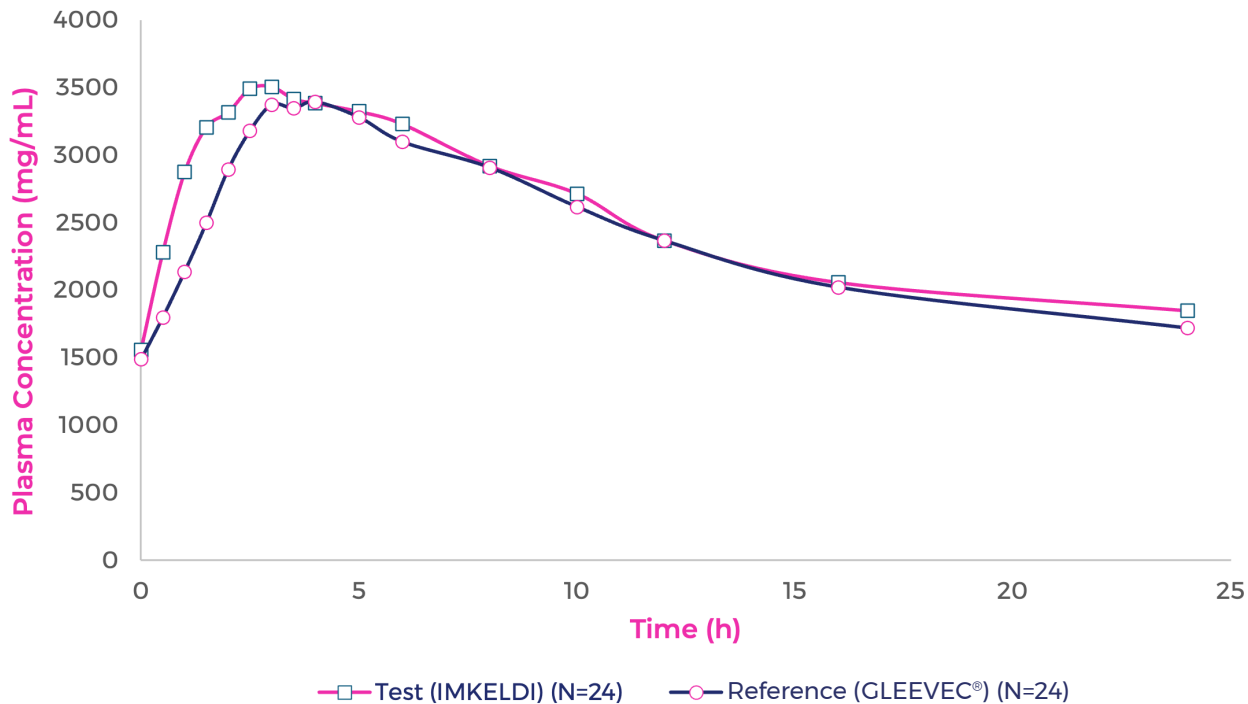
IMKELDI is a kinase inhibitor indicated for the treatment of:

- 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®

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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.<sup>1</sup>
- 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.<sup>2</sup>

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.

# 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 <sup>2</sup> /day
Pediatrics with Ph+ ALL	340 mg/m <sup>2</sup> /day

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

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

# 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

# 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

The Quick Start Program can provide up to 30 days of medication at no cost to patients when insurance approval takes more than 72 hours.

## Patient Assistance Program for Uninsured

Assistance is available for uninsured patients via form on [www.shorlaoncology.com/imkeldi](http://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.

## 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.

# Important Safety Information

## INDICATIONS

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## WARNING AND PRECAUTIONS

**Fluid Retention and Edema:** Imatinib can cause edema and occasionally serious fluid retention. Weigh and monitor patients regularly for signs and symptoms of fluid retention. Investigate unexpected rapid weight gain carefully and provide appropriate treatment. The probability of edema was increased with higher imatinib dose and age greater than 65 years in the CML studies. Severe superficial edema was reported in 1.5% of newly diagnosed CML patients taking imatinib, and in 2% to 6% of other adult CML patients taking imatinib. In addition, other severe fluid retention (e.g., pleural effusion, pericardial effusion, pulmonary edema, and ascites) reactions were reported in 1.3% of newly diagnosed CML patients taking imatinib, and in 2% to 6% of other adult CML patients taking imatinib. Severe fluid retention was reported in 9% to 13.1% of patients taking imatinib for GIST. In a randomized trial in patients with newly diagnosed Ph+ CML in chronic phase comparing imatinib and nilotinib, severe (Grade 3 or 4) fluid retention occurred in 2.5% of patients receiving imatinib and in 3.9% of patients receiving nilotinib 300 mg twice daily.

Effusions (including pleural effusion, pericardial effusion, ascites) or pulmonary edema were observed in 2.1% (none were Grade 3 or 4) of patients in the imatinib arm and 2.2% (0.7% Grade 3 or 4) of patients in the nilotinib 300 mg twice daily arm.

**Hematologic Toxicity:** Treatment with imatinib can cause anemia, neutropenia, and thrombocytopenia. Perform complete blood counts weekly for the first month, biweekly for the second month, and periodically thereafter as clinically indicated (for example, every 2 to 3 months). In CML, the occurrence of these cytopenias is dependent on the stage of disease and is more frequent in patients with accelerated phase CML or blast crisis than in patients with chronic phase CML. In pediatric CML patients the most frequent toxicities observed were Grade 3 or 4 cytopenias, including neutropenia, thrombocytopenia, and anemia. These generally occur within the first several months of therapy.

Please click [here](#) for full Prescribing Information.  
For more information, please visit [shorlaoncology.com/imkeldi](http://shorlaoncology.com/imkeldi).

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**Congestive Heart Failure and Left Ventricular Dysfunction:** Congestive heart failure and left ventricular dysfunction have been reported in patients taking imatinib. Cardiac adverse reactions were more frequent in patients with advanced age or co-morbidities, including previous medical history of cardiac disease. In an international randomized Phase 3 study in 1106 patients with newly diagnosed Ph+ CML in chronic phase, severe cardiac failure and left ventricular dysfunction were observed in 0.7% of patients taking imatinib compared to 0.9% of patients taking IFN + Ara-C. In another randomized trial with newly diagnosed Ph+ CML patients in chronic phase that compared imatinib and nilotinib, cardiac failure was observed in 1.1% of patients in the imatinib arm and 2.2% of patients in the nilotinib 300 mg twice daily arm and severe (Grade 3 or 4) cardiac failure occurred in 0.7% of patients in each group. Carefully monitor patients with cardiac disease or risk factors for cardiac or history of renal failure. Evaluate and treat any patient with signs or symptoms consistent with cardiac or renal failure.

**Hepatotoxicity:** Hepatotoxicity, occasionally severe, may occur with IMKELDI. Cases of fatal liver failure and severe liver injury requiring liver transplants have been reported with both short-term and long-term use of imatinib. Monitor liver function (transaminases, bilirubin, and alkaline phosphatase) before initiation of treatment and monthly, or as clinically indicated. Manage laboratory abnormalities with IMKELDI interruption and/or dose reduction. When imatinib is combined with chemotherapy, liver toxicity in the form of transaminase elevation and hyperbilirubinemia has been observed. Additionally, there have been reports of acute liver failure. Monitoring of hepatic function is recommended.

**Hemorrhage:** In a trial of imatinib versus IFN+Ara-C in patients with the newly diagnosed CML, 1.8% of patients had Grade 3/4 hemorrhage. In the Phase 3 unresectable or metastatic GIST studies, 211 patients (12.9%) reported Grade 3/4 hemorrhage at any site. In the Phase 2 unresectable or metastatic GIST study, 7 patients (5%) had a total of 8 CTC Grade 3/4 hemorrhages; gastrointestinal (GI) (3 patients), intra-tumoral (3 patients) or both (1 patient). Gastrointestinal tumor sites may have been the source of GI hemorrhages. In a randomized trial in patients with newly diagnosed Ph+ CML in chronic phase comparing imatinib and nilotinib, GI hemorrhage occurred in 1.4% of patients in the imatinib arm, and in 2.9% of patients in the nilotinib 300 mg twice daily arm. None of these events were Grade 3 or 4 in the imatinib arm; 0.7% were Grade 3 or 4 in the nilotinib 300 mg twice daily arm. In addition, gastric antral vascular ectasia has been reported in postmarketing experience.

**Gastrointestinal Disorders:** Imatinib can cause GI irritation. IMKELDI should be taken with food and a large glass of water to minimize this problem. There have been rare reports, including fatalities, of GI perforation.

**Hypereosinophilic Cardiac Toxicity:** In patients with hypereosinophilic syndrome with occult infiltration of HES cells within the myocardium, cases of cardiogenic shock/left ventricular dysfunction have been associated with HES cell degranulation upon the initiation of IMKELDI therapy. The condition was reported to be reversible with the administration of systemic steroids, circulatory support measures and temporarily withholding IMKELDI.

Myelodysplastic/myeloproliferative disease and systemic mastocytosis may be associated with high eosinophil levels. Consider performing an echocardiogram and determining serum troponin in patients with HES/CEL, and in patients with MDS/MPD or ASM associated with high eosinophil levels. If either is abnormal, consider prophylactic use of systemic steroids (1-2 mg/kg) for one to two weeks concomitantly with IMKELDI at the initiation of therapy.

**Dermatologic Toxicities:** Bullous dermatologic reactions, including erythema multiforme and Stevens-Johnson syndrome, have been reported with use of imatinib. In some cases of bullous dermatologic reactions, including erythema multiforme and Stevens-Johnson syndrome reported during post-marketing surveillance, a recurrent dermatologic reaction was observed upon rechallenge. Several foreign post-marketing reports have described cases in which patients tolerated the reintroduction of imatinib therapy after resolution or improvement of the bullous reaction. In these instances, imatinib was resumed at a dose lower than that at which the reaction occurred and some patients also received concomitant treatment with corticosteroids or antihistamines.



**Hypothyroidism:** Clinical cases of hypothyroidism have been reported in thyroidectomy patients undergoing levothyroxine replacement during treatment with imatinib. Monitor TSH levels in such patients.

**Embryo-Fetal Toxicity:** IMKELDI can cause fetal harm when administered to a pregnant woman. Imatinib mesylate was teratogenic in rats when administered during organogenesis at doses approximately equal to the maximum human dose of 800 mg/day based on body surface area (BSA). Significant post-implantation loss was seen in female rats administered imatinib mesylate at doses approximately one-half the maximum human dose of 800 mg/day based on BSA. Advise females of reproductive potential to use effective contraception (methods that result in less than 1% pregnancy rates) when using IMKELDI and for 14 days after stopping IMKELDI. Advise pregnant women of the potential risk to a fetus.

**Growth Retardation in Children and Adolescents:** Growth retardation has been reported in children and pre-adolescents receiving imatinib. The long-term effects of prolonged treatment with IMKELDI on growth in children are unknown. Therefore, monitor growth in children under IMKELDI treatment.

**Tumor Lysis Syndrome:** Cases of Tumor Lysis Syndrome (TLS), including fatal cases, have been reported in patients with CML, GIST, ALL, and eosinophilic leukemia receiving imatinib. The patients at risk of TLS are those with tumors having a high proliferative rate or high tumor burden prior to treatment. Monitor these patients closely and take appropriate precautions. Due to possible occurrence of TLS, correct clinically significant dehydration and treat high uric acid levels prior to initiation of IMKELDI.

**Impairments Related to Driving and Using Machinery:** Motor vehicle accidents have been reported in patients receiving imatinib. Advise patients that they may experience side effects, such as dizziness, blurred vision, or somnolence during treatment with IMKELDI. Recommend caution when driving a car or operating machinery.

**Renal Toxicity:** A decline in renal function may occur in patients receiving IMKELDI. Median estimated glomerular filtration rate (eGFR) values in patients on imatinib 400 mg daily for newly-diagnosed CML (four randomized trials) and malignant GIST (one single-arm trial) declined from a baseline value of 85 mL/min/1.73 m<sup>2</sup> (N = 1190) to 75 mL/min/1.73 m<sup>2</sup> at 12 months (N = 1082) and 69 mL/min/1.73 m<sup>2</sup> at 60 months (N = 549). Evaluate renal function prior to initiating IMKELDI and monitor during therapy, with attention to risk factors for renal dysfunction, such as preexisting renal impairment, diabetes mellitus, hypertension, and congestive heart failure.

**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 drug-related adverse reactions were edema, nausea and vomiting, muscle cramps, musculoskeletal pain, diarrhea and rash. Edema was most frequently periorbital or in lower limbs and was managed with diuretics, other supportive measures, or by reducing the dose of imatinib. The frequency of severe superficial edema was 1.5%-6%.

A variety of adverse reactions represent local or general fluid retention, including pleural effusion, ascites, pulmonary edema, and rapid weight gain with or without superficial edema. These reactions appear to be dose related, were more common in the blast crisis and accelerated phase studies (where the dose was 600 mg/day) and are more common in the elderly. These reactions were usually managed by interrupting imatinib treatment and using diuretics or other appropriate supportive care measures. These reactions may be serious or life threatening.

## DRUG INTERACTIONS

**Agents Inducing CYP3A Metabolism:** Consider alternative therapeutic agents with less enzyme induction potential in patients when rifampin or other strong CYP3A4 inducers are indicated for concomitant use with IMKELDI. The dosage of IMKELDI should be increased if concomitant use with a strong CYP3A4 inducer is required. Imatinib is a CYP3A substrate. Concomitant use with a strong CYP3A inducer decreases imatinib exposure, which may reduce imatinib efficacy.

**Agents Inhibiting CYP3A Metabolism:** Caution is recommended when administering IMKELDI with strong CYP3A4 inhibitors. Grapefruit juice should be avoided.

Imatinib is a CYP3A substrate. Concomitant use with a strong CYP3A inhibitor increases imatinib exposure, which may increase the risk of IMKELDI adverse reactions.

**Interactions With Drugs Metabolized by CYP3A4:** Use caution when administering IMKELDI with CYP3A4 substrates where minimal concentration changes may lead to serious adverse reactions. Because warfarin is metabolized by both CYP2C9 and CYP3A4, consider use of other anti-coagulants instead of warfarin in patients receiving IMKELDI who require anticoagulation.

Imatinib is a CYP3A inhibitor. Imatinib increases exposure of CYP3A substrates, which may increase the risk of adverse reactions related to these substrates.

**Interactions With Drugs Metabolized by CYP2D6:** Use caution when administering IMKELDI with CYP2D6 substrates where minimal concentration changes may lead to serious adverse reactions.

Imatinib is a CYP2D6 inhibitor. Imatinib increases exposure of CYP2D6 substrates, which may increase the risk of adverse reactions related to these substrates.

## USE IN SPECIFIC POPULATIONS

**Pregnancy:** IMKELDI can cause fetal harm when administered to a pregnant woman based on human and animal data. There are no clinical studies regarding use of IMKELDI in pregnant women. There have been postmarket reports of spontaneous abortions and congenital anomalies from women who have been exposed to imatinib during pregnancy. Reproductive studies in rats have demonstrated that imatinib mesylate induced teratogenicity and increased incidence of congenital abnormalities following prenatal exposure to imatinib mesylate at doses equal to the highest recommended human dose of 800 mg/day based on BSA. Advise pregnant women of the potential risk to a fetus.

The background risk of major birth defects and miscarriage for the indicated population is not known; however, in the U.S. general population, the estimated background risk of major birth defects of clinically recognized pregnancies is 2% to 4% and of miscarriage is 15% to 20%.

**Lactation:** Imatinib 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.

Based on data from 3 breastfeeding women taking imatinib, the milk:plasma ratio is about 0.5 for imatinib and about 0.9 for the active metabolite. Considering the combined concentration of imatinib and active metabolite, a breastfed child could receive up to 10% of the maternal therapeutic dose based on body weight.

**Females and Males of Reproductive Potential:** Based on human postmarketing reports and animal studies, IMKELDI can cause fetal harm.

**Pregnancy Testing:** Verify pregnancy status in females with reproductive potential prior to the initiation of treatment with IMKELDI.

**Contraception:** Advise female patients of reproductive potential to use effective contraception (methods that result in less than 1% pregnancy rates) when using IMKELDI during treatment and for fourteen days after stopping treatment with IMKELDI.

**Infertility:** The risk of infertility in females or males of reproductive potential has not been studied in humans. In a rat study, the fertility in males and females was not affected.

**Geriatric Use:** In the CML clinical studies, approximately 20% of patients were older than 65 years. In the study of patients with newly diagnosed CML, 6% of patients were older than 65 years. The frequency of edema was higher in patients older than 65 years as compared to younger patients; no other difference in the safety profile was observed. The efficacy of imatinib was similar in older and younger patients.

In the unresectable or metastatic GIST study, 16% of patients were older than 65 years. No obvious differences in the safety or efficacy profile were noted in patients older than 65 years as compared to younger patients, but the small number of patients does not allow a formal analysis.

In the adjuvant GIST study, 221 patients (31%) were older than 65 years. No difference was observed in the safety profile in patients older than 65 years as compared to younger patients, with the exception of a higher frequency of edema. The efficacy of imatinib was similar in patients older than 65 years and younger patients.

**Hepatic Impairment:** Reduce the dose by 25% for patients with severe hepatic impairment. Patients with mild hepatic impairment (total bilirubin  $\leq$  upper limit of normal [ULN] and aspartate aminotransferase [AST]  $>$  ULN, or total bilirubin  $>$  1 to 1.5 times ULN and any value for AST) and moderate hepatic impairment (total bilirubin  $>$  1.5 to 3 times ULN and any value for AST) do not require a dose adjustment.

The effect of hepatic impairment on the pharmacokinetics of both imatinib and its major metabolite, CGP74588, was assessed in 84 patients with cancer with varying degrees of hepatic impairment at imatinib doses ranging from 100 mg to 800 mg. Mild hepatic impairment (total bilirubin  $\leq$  ULN and aspartate aminotransferase [AST]  $>$  ULN, or total bilirubin  $\leq$  1.5 times ULN and any value for AST) and moderate hepatic impairment (total bilirubin  $>$  1.5 to 3 times ULN and any value for AST) do not influence exposure to imatinib and CGP74588. In patients with severe hepatic impairment, (total bilirubin  $>$  3 to 10 times ULN and any value for AST), the imatinib C<sub>max</sub> and area under curve (AUC) increased by 63% and 45% and the CGP74588 C<sub>max</sub> and AUC increased by 56% and 55%, relative to patients with normal hepatic function.

**Renal Impairment:** Dose reductions are necessary for patients with moderate and severe renal impairment. The effect of renal impairment on the pharmacokinetics of imatinib was assessed in 59 patients with cancer and varying degrees of renal impairment at single and steady state imatinib doses ranging from 100 to 800 mg/day. The mean exposure to imatinib (dose normalized AUC) in patients with mild (CL<sub>cr</sub> = 40-59 mL/min) and moderate renal impairment (CL<sub>cr</sub> = 20-39 mL/min) increased 1.5- to 2-fold compared to patients with normal renal function. There are not sufficient data in patients with severe renal impairment (CL<sub>cr</sub> = less than 20 mL/min).



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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](http://www.fda.gov/medwatch).

**For Print: Please see the accompanying full Prescribing Information.**

**For Digital: Please click [here](#) for full Prescribing Information.**

For more information, please visit [shorlaoncology.com/imkeldi](http://shorlaoncology.com/imkeldi).