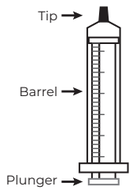
Imkeldi (imatinib) Oral Solution

SHORLA ONCOLOGY®

This guide contains information on how to withdraw and administer IMKELDI



Oral Dispensing Syringe *(not included)*


Bottle


Bottle Adapter *(not included)*


Disposable Gloves *(not included)*

Please read this instruction guide completely before beginning. Each pack of IMKELDI contains a bottle of medicine with a cap in an amber child-resistant tamper-evident bottle. Ask your pharmacist to provide the appropriate bottle adapter and syringe. A household teaspoon is NOT an accurate dosing device. Always wash hands thoroughly and use disposable gloves when handling IMKELDI.

When Preparing a New Bottle

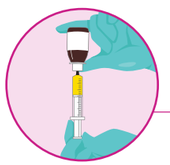
Remove the child-resistant bottle cap by pushing it down firmly and twisting counter-clockwise. Place the open bottle upright on a clean flat surface. Hold the bottle firmly and push the ribbed end of the bottle adapter firmly in the neck of the bottle as far as it will go.

1

Check your prescription to find out the number of mL you are supposed to take. Find the number line on the oral dispensing syringe barrel that matches your dose. Push the plunger of the oral dispensing syringe all the way up towards the tip of the oral dispensing syringe to remove air.

2

While keeping the bottle in an upright position, push tip of dosing syringe into the hole in the adaptor.



3

Carefully turn bottle upside down. Pull syringe plunger back slowly until the widest part of the white syringe plunger lines up with the mark on the syringe indicating prescribed dose. If there are air bubbles, push medicine back into the bottle and redraw until no bubbles remain.

4

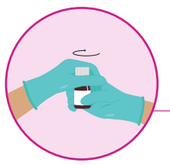
Return bottle to an upright position, remove syringe from the adaptor, and hold the syringe by the barrel.

5

Check syringe for correct dose. Sit up or stand before taking medicine. Place the syringe tip in your mouth and direct it to the inside of your cheek. Push the plunger slowly until it no longer moves and the medicine is out of the dispensing syringe.

6

Swallow medicine and then eat a meal and drink a glass of water.



7

Put the cap back on the bottle leaving the adaptor in place and close it tightly.

8

Immediately after use, wash the syringe with warm, soapy water. Draw the plunger in and out under water to remove medicine. Remove plunger, wash thoroughly, and rinse with cold water. Dry with a paper towel. Ensure all parts are fully dry before reuse.

IMPORTANT information you need to know before taking IMKELDI

Please see Important Safety Information on the back of this guide.

- All doses of IMKELDI should be taken with a meal and a large glass of water.
- **Most common side effects of IMKELDI**
  - Swelling (edema), nausea, vomiting, muscle cramps and pain, diarrhea, rash, tiredness, and stomach pain
  - IMKELDI may cause dizziness, blurred vision, or sleepiness during treatment

These are not all the possible side effects of IMKELDI. Call your healthcare provider if you experience any side effects.

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

How should I store and dispose of IMKELDI?

- Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Store and dispense in original container only. Any open bottle should be discarded after 30 days.
- **IMKELDI is a hazardous drug. Ask your oncology team where to return and unused medication for disposal. Do not flush down the toilet or throw in the trash.**

IMKELDI (imatinib) Oral Solution, 80 mg/mL

What is IMKELDI?
IMKELDI is a prescription medicine used to treat:

- 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-PDGFRα 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-PDGFRα 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.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about IMKELDI?

IMKELDI can cause serious side effects, including:

Fluid Retention and Edema: Contact your healthcare provider if unexpected rapid weight gain occurs.

Decreased Blood Cell Counts: IMKELDI can affect your bone marrow and cause decreases in red blood counts, white blood cell counts, and platelets that can be severe and life-threatening. Your healthcare provider will check your blood cell counts when you start and during treatment with IMKELDI.

Congestive Heart Failure or Other Heart Abnormalities: Severe congestive heart failure and other heart abnormalities can occur with IMKELDI. Contact your healthcare provider if unexpected rapid weight gain occurs.

Liver Problems: IMKELDI can cause liver problems which may sometimes be severe including liver failure or death. You should immediately contact your healthcare provider if signs of liver failure occur, including jaundice (yellowing of your skin or the white part of your eyes), anorexia, bleeding, or bruising.

Bleeding: Bleeding may occur in IMKELDI-treated patients with certain types of cancers. Contact your healthcare provider if you are at risk for bleeding while taking IMKELDI.

Stomach and Intestine (gastrointestinal) Problems: IMKELDI can cause GI or stomach irritation. Take IMKELDI with food and a large glass of water to minimize this problem. A tear in the intestinal wall (perforation) has been reported with IMKELDI use and may, on rare occasions, cause death.

Serious Skin Reactions: Serious skin reactions can happen with IMKELDI. Tell your healthcare provider right away about any new or worsening skin rash during treatment with IMKELDI.

Thyroid Problems: IMKELDI may lower your thyroid hormone. Your healthcare provider will monitor your thyroid levels and may recommend medication to control your thyroid levels.

Harm to an unborn baby, including birth defects or death of an unborn baby.

Females who can become pregnant:

- Your healthcare provider should do a pregnancy test before you start taking IMKELDI to see if you are pregnant.
- Use effective birth control during treatment and for 14 days after your last dose of IMKELDI.
- Ask your healthcare provider what forms of birth control you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with IMKELDI.
- You should avoid breastfeeding during treatment with IMKELDI and for 1 month after the last dose of IMKELDI.

Growth Retardation in Children: Growth retardation has been reported in children and pre-adolescents receiving IMKELDI. Long-term effects on growth in children are unknown. Your healthcare provider should monitor growth in children treated with IMKELDI.

Tumor Lysis Syndrome: Tumor lysis syndrome is caused by the fast breakdown of cancer cells. Tumor lysis syndrome can cause kidney failure and the need for dialysis treatment, abnormal heart rhythm, seizure, and sometimes death. Your healthcare provider may do blood tests to check for tumor lysis syndrome if you are receiving IMKELDI.

Drug Interactions: IMKELDI and certain other medicines, such as warfarin, erythromycin, and phenytoin, including over-the-counter medications, such as herbal products, can interact with each other. Tell your healthcare provider if you are taking or plan to take iron supplements. Avoid grapefruit juice and other foods known to interact with IMKELDI. Talk to your healthcare provider about all the medicines you take.

Driving and Using Machines: You may experience dizziness, blurred vision, or sleepiness while taking IMKELDi. Car accidents have been reported in patients receiving iMKELDI. Caution should be taken when driving a car or operating machinery.

Kidney Problems: Kidney problems can happen with IMKELDI. Your healthcare provider will check your kidney function before you start and during treatment with IMKELDI. Tell your healthcare provider right away if you have any signs or symptoms of kidney problems, including:

- a big change (either increase or decrease) in the amount of urine you produce
- swelling in your legs, ankles or feet
- shortness of breath
- tiredness
- weight gain

Accurate Measuring Device and Dosage and Administration: When taking IMKELDI, you should measure IMKELDI with an accurate milliliter measuring device. A household teaspoon is not an accurate measuring device and could lead to overdosage, which can result in serious adverse reactions. Ask your pharmacist to recommend an appropriate press-in bottle adapter and oral dispensing syringe and for instructions for measuring the correct dose. IMKELDI should be taken with a meal and a large glass of water. If a dose is missed, wait until the next scheduled dose and do not take two doses at the same time. Take IMKELDI exactly as prescribed, do not change your dose or stop taking IMKELDI unless you are told to do so by your healthcare provider. Read the Instructions for Use before you (or your child) start using IMKELDI oral solution, and each time you get a refill. There may be new information. This important information does not take the place of talking to your (or your child's) healthcare provider about your (or your child's) medical condition or treatment.

What are the most common side effects of IMKELDI?

- Swelling (edema), nausea, vomiting, muscle cramps and pain, diarrhea, rash, tiredness, and stomach pain
- IMKELDI may cause dizziness, blurred vision, or sleepiness during treatment

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Please click here for full Prescribing Information.

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