MEDICATION GUIDE
KOMZIFTI (kom-ZIF-tee)
(ziftomenib) capsules

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

KOMZIFTI can cause serious side effects including:

Differentiation Syndrome. Differentiation syndrome is a condition that affects your blood cells that is common during treatment with KOMZIFTI and can be life-threatening or lead to death if not treated. Differentiation syndrome can happen as early as 3 days after you start KOMZIFTI treatment and can also happen later during treatment with KOMZIFTI. Tell your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following signs or symptoms of differentiation syndrome during treatment with KOMZIFTI:

- fever
- joint or bone pain
- dizziness
- shortness of breath or trouble breathing
- cough
- chest pain
- rapid weight gain
- rash
- decreased urine output
- swelling of hands, feet, ankles, or legs

If you develop signs and symptoms of differentiation syndrome during treatment with KOMZIFTI, your healthcare provider may temporarily stop KOMZIFTI and give you a corticosteroid medicine. Your healthcare provider will monitor you until your signs and symptoms improve.

See "**What are the possible side effects of KOMZIFTI?**" for more information about side effects.

What is KOMZIFTI?

KOMZIFTI is a prescription medicine used to treat adults with acute myeloid leukemia (AML) with a nucleophosmin 1 (*NPM1*) mutation whose AML has come back or did not improve after previous treatment(s) and who have no other satisfactory treatment options.

Your healthcare provider will perform a test to make sure that KOMZIFTI is right for you.
It is not known if KOMZIFTI is safe and effective in children.

Before taking KOMZIFTI, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including a condition called long QT syndrome.
- have problems with abnormal levels of salts in your blood (electrolytes), such as potassium and magnesium levels.
- are pregnant or plan to become pregnant. KOMZIFTI can harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider will perform a pregnancy test before you start treatment with KOMZIFTI.
  - Use effective birth control (contraception) during treatment with KOMZIFTI and for 6 months after the last dose.

  Males who have female partners who are able to become pregnant:
  - Use effective birth control (contraception) during treatment with KOMZIFTI and for 3 months after the last dose.
  - Talk to your healthcare provider about birth control methods you can use during this time.
- are breastfeeding or plan to breastfeed. It is not known if KOMZIFTI passes into your breast milk. Do not breastfeed during your treatment with KOMZIFTI and for 2 weeks after your last dose.

Tell your healthcare provider about any other medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
KOMZIFTI and other medicines may affect each other causing side effects. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

How should I take KOMZIFTI?

- Take KOMZIFTI exactly as your healthcare provider tells you to.
- Do not change your dose or stop taking KOMZIFTI without talking to your healthcare provider.
- Take KOMZIFTI 1 time a day around the same time each day.
- Take KOMZIFTI on empty stomach, at least 1 hour before or 2 hours after a meal.
- Swallow KOMZIFTI capsules whole. Do not open, break, or chew the capsules.
- If you take medicine to reduce stomach acid:
  - Avoid taking a proton pump inhibitor (PPI) medicine with KOMZIFTI.
  - Take KOMZIFTI either 2 hours before or 10 hours after taking an H2 receptor blocker medicine.
  - Take KOMZIFTI either 2 hours before or 2 hours after taking a locally acting antacid medicine (such as calcium carbonate).
- If you miss a dose of KOMZIFTI or did not take it at the usual time, take your dose as soon as possible and at least 12 hours before your next scheduled dose. Return to your normal schedule the following day. Do not take 2 doses within 12 hours of each other to make up for the missed dose.

What are the possible side effects of KOMZIFTI?
KOMZIFTI can cause serious side effects, including:

- **See "What is the most important information I should know about KOMZIFTI?"**
- **Changes in electrical activity of your heart (QT prolongation)**. Changes in the electrical activity of your heart may lead to irregular heartbeats (rhythm) that can be life-threatening or lead to death. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and will also do blood tests to check your potassium and magnesium levels before and during treatment with KOMZIFTI. Tell your healthcare provider right away if you feel faint, lightheaded, or dizzy, or if you have shortness of breath, or if you feel your heart beating irregularly or fast during treatment with KOMZIFTI.

The most common side effects of KOMZIFTI include:

- infections including bacterial infections
- bleeding
- diarrhea
- nausea
- feeling tired
- swelling in the arms and legs
- muscle, bone, and joint pain
- itching
- fever with decreased white blood cell counts
- changes in liver function tests

Your healthcare provider may decrease your dose, temporarily stop, or completely stop your treatment with KOMZIFTI if you develop certain side effects during treatment with KOMZIFTI.

KOMZIFTI may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of KOMZIFTI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KOMZIFTI?

- Store KOMZIFTI at room temperature between 68°F to 77°F (20°C to 25°C).
- KOMZIFTI comes in a container with a child-resistant cap.

Keep KOMZIFTI and all medicines out of the reach of children.

General information about the safe and effective use of KOMZIFTI.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take KOMZIFTI for conditions for which it was not prescribed. Do not give KOMZIFTI to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about KOMZIFTI that is written for health professionals.

What are the ingredients in KOMZIFTI?
Active ingredient: ziftomenib
Inactive ingredients: croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, and sodium lauryl sulfate.
The capsule shells imprinted with black ink contain: hypromellose and titanium dioxide.

Manufactured for: Kura Oncology, Inc., San Diego, CA 92121

For more information, go to www.komzifti.com or call Kura at 1-844-587-2662 US-KO539-2500155 11/25
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