PATIENT INFORMATION
EKITNA™ (ee kit' nah)
(bezuclastinib)
tablets, for oral use

What is the most important information I should know about EKITNA?
EKITNA can cause serious side effects, including:

- **Liver problems.** EKITNA in combination with sunitinib can cause liver problems that can be severe. Your healthcare provider will do blood tests to check your liver before you start and during treatment with EKITNA.

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

What is EKITNA?
EKITNA is a prescription medicine used in combination with a medicine called sunitinib, to treat adults with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with imatinib.
It is not known if EKITNA is safe and effective in children.

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

- are pregnant or plan to become pregnant. EKITNA can harm your unborn baby.
  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with EKITNA.
  - Use effective non-hormonal birth control (contraception) during treatment with EKITNA and for 2 weeks after your last dose.
  - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with EKITNA.

  Males with female partners who are able to become pregnant:
  - Use effective birth control (contraception) during treatment with EKITNA and for 2 weeks after your last dose.
- are breastfeeding or plan to breastfeed. It is not known if EKITNA passes into your breast milk. **Do not** breastfeed during treatment with EKITNA and for 2 weeks after your last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
EKITNA and certain other medicines can affect each other causing side effects and affect how the medicines work.

How should I take EKITNA?

- Take EKITNA exactly as your healthcare provider tells you to take it.
- Take EKITNA 1 time a day.
- Take EKITNA on an empty stomach, at least 1 hour before or 2 hours after food.
- Swallow EKITNA tablets whole. Do not crush, break, or dissolve the tablets.
- If you miss a dose, skip the missed dose and take your next dose at your scheduled time. **Do not** take 2 doses to make up the missed dose.
- If you vomit after taking a dose, do not take another dose. Take your next dose at your scheduled time.

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

- See **"What is the most important information I should know about EKITNA?"**

The most common side effects of EKITNA include:

- diarrhea
- increase in liver function tests
- high blood pressure
- change in taste
- nausea
- change in hair color
- tiredness
- stomach area (abdominal) pain
- vomiting
- decreased appetite
- sores in the mouth
- heartburn (GERD)
- rash
- indigestion
- fever

The most common severe abnormal blood tests include increased liver enzymes, decreased white blood cell counts, and decreased red blood cell counts.

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with EKITNA if you develop certain side effects.
EKITNA 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 EKITNA.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You may also report side effects to Cogent Biosciences, Inc. by calling 1-844-264-3688.

How should I store EKITNA?

- Store EKITNA at room temperature between 68°F to 77°F (20°C to 25°C).
- Close the bottle tightly after each dose.
- The bottle contains a desiccant to help keep the tablets dry (protect from humidity). Keep the desiccant in the bottle.
- EKITNA bottle comes with a child-resistant closure.

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

General information about the safe and effective use of EKITNA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EKITNA for a condition for which it was not prescribed. Do not give EKITNA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about EKITNA that is written for health professionals.

What are the ingredients in EKITNA?

Active ingredient: bezuclastinib

Inactive ingredients: butylated hydroxytoluene, colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, mannitol, microcrystalline cellulose, and sodium stearyl fumarate

Distributed by Cogent Biosciences, Inc., 180 Third Avenue, 4th Floor, Waltham, MA 02451
Made in Spain.
For more information, call 1-844-264-3688 or visit www.EKITNA.com.
This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 11/2026

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