MEDICATION GUIDE

PIMJETMI® (pim-JET-mee)

(pimicotinib)

capsules

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

PIMJETMI can cause serious side effects, including:

Liver problems. Increased liver enzymes in your blood are common with PIMJETMI. Your healthcare provider will do blood tests to check for liver problems:

- before starting treatment with PIMJETMI,
- every month for the first 3 months,
- then every 3 months for the rest of the first year after starting treatment and as needed thereafter during treatment with PIMJETMI.

If you develop liver problems during treatment with PIMJETMI, your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop treatment depending on how severe your liver problems are.

Tell your healthcare provider right away if you develop any signs or symptoms of liver problems during treatment with PIMJETMI:

- yellowing of your skin or the white part of your eyes
- dark urine
- lack or loss of appetite
- pain or tenderness on the upper right side of your stomach-area (abdomen)
- feeling overly tired
- nausea
- vomiting
- fever
- rash
- itching

See "What are the possible side effects of PIMJETMI?" for information about side effects.

What is PIMJETMI?

PIMJETMI is a prescription medicine used to treat adults with symptomatic tenosynovial giant cell tumor (TGCT) when surgery may make the symptoms worse or cause severe problems.

It is not known if PIMJETMI is safe and effective in children.

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

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

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

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking PIMJETMI with certain other medicines may affect how PIMJETMI works and can cause side effects.

How should I take PIMJETMI?

- Take PIMJETMI exactly as your healthcare provider tells you to take it.
- Take PIMJETMI 1 time a day.
- Take PIMJETMI with food or without food.
- Swallow PIMJETMI capsules whole. **Do not** open, break, or chew the capsules.
- If you miss a dose of PIMJETMI within 12 hours of your scheduled time, take the missed dose as soon as possible. If you miss your dose by more than 12 hours, skip the missed dose and take your next dose at your regularly scheduled time.
- If you vomit after taking a dose of PIMJETMI, do not take another dose and take the next dose at your regularly scheduled time.

What are the possible side effects of PIMJETMI?
PIMJETMI can cause serious side effects.
See "What is the most important information I should know about PIMJETMI?"

The most common side effects of PIMJETMI include:

- itching
- rash
- swelling of your face
- swelling around your eyes
- tiredness
- nausea
- headache
- swelling of your hands and feet
- change in certain blood tests

PIMJETMI may affect fertility in males, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of PIMJETMI.
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 PIMJETMI?

- Store PIMJETMI at room temperature between 68°F to 77° F (20°C to 25°C).
- PIMJETMI comes in a bottle with a child-resistant closure.
- PIMJETMI comes with a drying agent (desiccant) in the bottle. Store PIMJETMI in the original bottle with desiccant.
- Keep the bottle closed to protect from moisture.

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

General information about the safe and effective use of PIMJETMI

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use PIMJETMI for a condition for which it was not prescribed. Do not give PIMJETMI 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 PIMJETMI that is written for health professionals.

What are the ingredients in PIMJETMI?

Active ingredient: pimicotinib hydrochloride

Inactive ingredient: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. The capsule shell, imprinted with black ink, contains the following inactive ingredients: black iron oxide, butyl alcohol, dehydrated alcohol, gelatin, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution, and titanium dioxide.

Manufactured for: EMD Serono, Inc, Boston, MA 02210, U.S.A.
PIMJETMI is a trademark of Merck KGaA, Darmstadt, Germany.
For more information, call 1-844-826-8371 or go to www.PIMJETMI.com.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued 11/2026