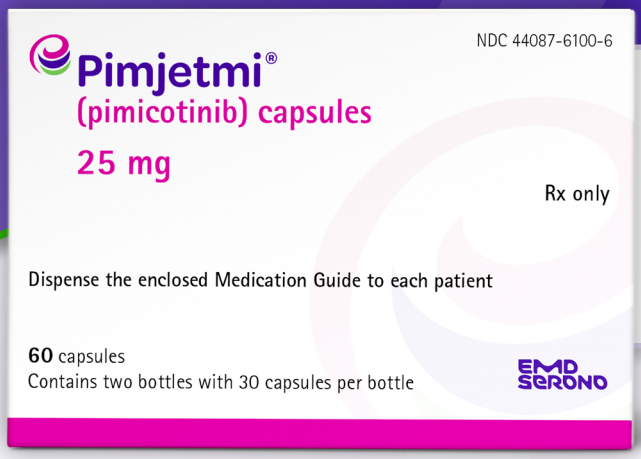
Pimjetmi®
(pimicotinib) 25 mg hard capsules

Available Through NCODA Endorsed Oncology Optimized Limited Distribution Model



This medication meets the criteria for Oncology Optimized Limited Distribution

The PIMJETMI distribution and dispensing model is designed to optimize the provider and patient experience

- Ensures **CONTINUITY OF CARE** for patients
- Supports **TIMELY ACCESS** to therapy
- Maximizes **PRESCRIPTION RETENTION**

Contact your Specialty Distributor Partner to determine whether your pharmacy qualifies for network access.

EMD Serono, Inc. and SpringWorks Therapeutics, Inc. are committed to supporting medically integrated dispensing pharmacies through a distribution model that promotes in-practice care and timely patient-centered treatment.

Learn more about NCODA's Oncology Optimized Limited Distribution model at NCODA.org/OOLD/

Join NCODA today.
To register for a complimentary NCODA membership, **please visit NCODA.org/register**

NCODA=Network for Collaborative Oncology Development & Advancement.

INDICATIONS & USAGE

PIMJETMI (pimicotinib) is indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection may cause worsening functional limitations or severe morbidity.

IMPORTANT SAFETY INFORMATION

SUMMARY OF WARNINGS & PRECAUTIONS:

PIMJETMI (pimicotinib) is associated with the following Warnings & Precautions: Hepatotoxicity; Embryo-Fetal Toxicity; & Increased Serum Creatinine without Affecting Renal Function.

Please see additional Important Safety Information on next page and click here for full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS & PRECAUTIONS

Hepatotoxicity:

- Cases of serious & fatal liver injury have occurred with the use of another kinase inhibitor that targets colony-stimulating factor-1 receptor (CSF-1R). Serious & fatal liver injury have not been observed with PIMJETMI.
- Elevated aspartate aminotransferase (AST) & alanine aminotransferase (ALT) can occur with PIMJETMI.
- Avoid PIMJETMI in patients with pre-existing active liver or biliary disease.
- Monitor liver function tests (including AST, ALT, alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT) & total bilirubin), prior to initiation of PIMJETMI, monthly for the first 3 months then every 3 months for the first year of therapy & as clinically indicated thereafter. Withhold & reduce the dose, or permanently discontinue PIMJETMI based on the severity of the liver transaminase elevations.

Embryo-Fetal Toxicity:

- PIMJETMI can cause fetal harm when administered to pregnant women. Advise pregnant women on the potential risk to the fetus.
- Advise females of reproductive potential & males with female partners of reproductive potential to use effective contraception during treatment with PIMJETMI & for 2 weeks after the last dose.

Increased Serum Creatinine without Affecting Renal Function:

- Increases in serum creatinine can occur with the use of PIMJETMI. These increases in serum creatinine may not be associated with changes in renal function. Increases in creatinine reversed upon PIMJETMI discontinuation. During PIMJETMI treatment, use alternative measures that are not based on serum creatinine to assess renal function.

Adverse Reactions:

The most common (>20%) adverse reactions were pruritus, rash, face edema, periorbital edema, fatigue, nausea, headache, & peripheral edema.

The most common (>30%) lab abnormalities were creatine phosphokinase increased, lactate dehydrogenase increased, AST increased, lipase increased, cholesterol increased, amylase increased, & ALT increased.

Drug Interactions:

- Strong & Moderate CYP3A Inhibitors: Avoid concomitant use of strong & moderate CYP3A inhibitors with PIMJETMI. If concomitant use cannot be avoided, reduce the PIMJETMI dosage (see Dosage & Administration).
- Strong & Moderate CYP3A Inducers: Avoid concomitant use of strong & moderate CYP3A inducers with PIMJETMI. If concomitant use of a moderate CYP3A inducer cannot be avoided, increase the PIMJETMI dosage (see Dosage & Administration).

Lactation: Advise females not to breastfeed during treatment with PIMJETMI & for 2 weeks after the last dose.

Please see click here for full Prescribing Information.

EMD SERONO

SpringWorks THERAPEUTICS

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