The TURALIO REMS (Risk Evaluation and Mitigation Strategy) is a safety program that manages the risks of serious and potentially fatal liver injury from TURALIO. The TURALIO REMS is required by the Food and Drug Administration (FDA) to ensure the potential benefits of TURALIO outweigh its risks.

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If you have questions about TURALIO REMS or need help with certification or enrollment, call 1-833-TURALIO (1-833-887-2546). Monday-Friday, 8:00am – 8:00pm ET

To learn more about the serious risks associated with TURALIO, please refer to the Prescribing Information including Boxed Warning and the Medication Guide.

Indication

TURALIO™ (pexidartinib) is indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.
Prescriber Overview

TURALIO is only available through the TURALIO REMS. In order for a healthcare provider to prescribe TURALIO, they must become certified.

Complete Prescriber Training and Certification Online

To become certified in the TURALIO REMS via fax or email, prescribers must complete the following steps:

step 1 Read the TURALIO Prescribing Information

step 2 Read the Program Overview and the Prescriber Training

step 3 Complete and submit the Prescriber Knowledge Assessment and the Prescriber Enrollment Form to the TURALIO REMS
   3a. Via FAX (1-833-TRL-REMS)
   3b. Via email at Enroll@TURALIOREMS.com

Prescribers will be notified when their certification in the TURALIO REMS is complete and they can prescribe TURALIO.
TURALIO is only available through the TURALIO REMS by certified pharmacies.

To become certified to dispense TURALIO, pharmacies must complete the following steps:

**step 1**  Designate Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS

**step 2**  Authorized Representative must review the Program Overview

**step 3**  Authorized Representative must attest that the pharmacy will follow REMS requirements by completing and submitting a Pharmacy Enrollment Form to the TURALIO REMS

3a. By fax at 1-833-TRL-REMS (1-833-875-7367)

3b. By email at Enroll@TURALIOREMS.com

**step 4**  Authorized Representatives will be notified when their pharmacy’s certification in the TURALIO REMS is complete and they can dispense TURALIO.

**step 5**  Prior to dispensing TURALIO, the Authorized Representative must train all relevant pharmacy staff on TURALIO using the Program Overview.

**step 6**  Before Dispensing:

6a. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified and the patient is enrolled in the REMS

6b. Dispense no more than a 30 days supply for the first 3 months of treatment
Patients who are prescribed TURALIO must be enrolled in TURALIO REMS by your doctor.

Materials for Patients

- Medication Guide
- Patient Guide

To report adverse events of TURALIO, please contact the REMS at 1-833-TURALIO (1-833-887-2546), Daiichi Sankyo, Inc. at 1-877-4DS-PROD (1-877-437-7763) or FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

TURALIO is a registered trademark of Daiichi Sankyo Company Limited.
Contact Us

Phone
1-833-TURALIO
(1-833-887-2546)

Fax
1-833-TRL-REMS
(1-833-875-7367)

Hours of Operation
Monday - Friday
8:00-8:00 PM Eastern

For more information on TURALIO, please read the Medication Guide and the Patient Guide.

To report any adverse events, product quality complaints, medication errors, or pregnancies associated with the use of TURALIO, contact:
the REMS at 1-833-TURALIO (1-833-887-2546),
Daiichi Sankyo, Inc. at 1-877-4DS-PROD (1-877-437-7763) or
FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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JEFFERY L SUMMERS
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