



## Welcome to the TURALIO® REMS (Risk Evaluation and Mitigation Strategy)

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.

### Prescribers

Prescribers must become certified in TURALIO REMS to prescribe TURALIO.

[Learn about Prescriber Certification.](#)

[LEARN MORE](#)

### Pharmacies

Pharmacies must become certified in TURALIO REMS to dispense TURALIO.

[Learn about Pharmacy Certification.](#)

[LEARN MORE](#)

### Patients

Patients who are prescribed TURALIO must be enrolled in TURALIO REMS.

[Learn about Patient Enrollment.](#)

[LEARN MORE](#)

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.

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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## Welcome to the TURALIO® REMS (Risk Evaluation and Mitigation Strategy)

### 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](#)

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- step 2 Read the [Program Overview](#) and the [Prescriber Training](#)

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- 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](mailto:Enroll@TURALIOREMS.com)

Prescribers will be notified when their certification in the TURALIO REMS is complete and they can prescribe TURALIO.

#### Materials for Healthcare Providers

- [Letter for Healthcare Provider](#)
- [Letter for Professional Societies](#)
- [Program Overview](#)
- [Prescriber Training](#)
- [Prescriber Knowledge Assessment](#)
- [Prescriber Enrollment Form](#)
- [Patient Enrollment Form](#)
- [Patient Status Form](#)
- [Liver Adverse Event Reporting Form](#)

#### 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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## Welcome to the TURALIO® REMS (Risk Evaluation and Mitigation Strategy)

### Pharmacies

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

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- step 2** Authorized Representative must review the [Program Overview](#)

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- 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](mailto:Enroll@TURALIOREMS.com)

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

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- step 5** Prior to dispensing TURALIO, the Authorized Representative must train all relevant pharmacy staff on TURALIO using the [Program Overview](#).

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- 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

#### Materials for Pharmacies

[Program Overview](#)

[Pharmacy Enrollment Form](#)

[Liver Adverse Event Reporting Form](#)

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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## Welcome to the TURALIO® REMS (Risk Evaluation and Mitigation Strategy)

### Patients

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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## Welcome to the TURALIO® REMS (Risk Evaluation and Mitigation Strategy)

### 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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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## Welcome to the TURALIO® REMS (Risk Evaluation and Mitigation Strategy)

### Login

#### Login

Login is available to certified prescribers and other users authorized by the REMS Coordinating Center.

LOGIN

[Forgot Username](#)

OR

Don't have an online account?

#### Register

To create your web account for the TURALIO REMS, please enter your NPI Number and click "Continue".

**Note:** Online registration is required for Prescribers only.

\* NPI Number

CONTINUE

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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