

**TURALIO™ (pexidartinib)
Risk Evaluation and Mitigation Strategy
(REMS)**

PROGRAM OVERVIEW



If you have any questions regarding the REMS, please visit www.TURALIOREMS.com or call 1-833-TURALIO (1-833-887-2546).

Please see Prescribing Information for complete safety profile of TURALIO.

What is TURALIO™?

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.

Warning: Hepatotoxicity

- **TURALIO can cause serious and potentially fatal liver injury.**
- **Monitor liver tests prior to initiation of TURALIO and at specified intervals during treatment.**
- **Withhold and dose reduce or permanently discontinue TURALIO based on severity of hepatotoxicity.**

See the **Prescribing Information** for TURALIO for more information on the risk of hepatotoxicity, liver monitoring frequency and dose reductions.

What is the TURALIO REMS?

This Risk Evaluation and Mitigation Strategy (REMS), is a safety program, required by the Food and Drug Administration (FDA), to ensure the potential benefits of TURALIO outweigh its risks.

TURALIO is available only through the TURALIO REMS, a restricted distribution program.

What do Healthcare Providers Need to Do Before Prescribing TURALIO?

Prescribers of TURALIO must become certified to prescribe. To become certified, prescribers must complete the following steps:

Step 1:	Review the TURALIO Prescribing Information
Step 2:	Review the Program Overview (this document) and the Prescriber Training
Step 3:	Complete and submit the Prescriber Knowledge Assessment to the TURALIO REMS
Step 4:	Complete and submit the Prescriber Enrollment Form to the TURALIO REMS

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

Prior to initiating treatment:

- counsel patients on 1) the risk of serious and potentially fatal liver injury, 2) liver test monitoring prior to and during treatment with TURALIO, and to 3) report any signs and/or symptoms of liver injury during therapy.
- enroll patient into a patient registry by completing and submitting the **Patient Enrollment Form** to the REMS.
- distribute and use the **Patient Guide** to educate and communicate these messages.
- assess the patient by obtaining liver tests.

During treatment:

- monitor the patient's liver tests and modify the TURALIO dose per the **Prescribing Information**.
- complete and submit the **Patient Status Form** to the REMS
 - monthly for the first 3 months of TURALIO treatment,
 - then every 3 months until one year of treatment,
 - then every 6 months thereafter.

Prescriptions should be limited to a 30 days' supply for each of the first 3 months of treatment.

Please see Prescribing Information for complete safety profile of TURALIO.

Adverse Event Reporting:

Prescribers should always report all adverse events including those of serious and potentially fatal liver injury by contacting the REMS at 1-833-TURALIO (1-833-887-2546), to Daiichi Sankyo, Inc. at 1-877-4DS-PROD (1-877-437-7763) or to FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Report liver adverse events using the *Liver Adverse Event Reporting Form*.

What do Pharmacists Need to Do Before Dispensing TURALIO?

TURALIO may only be dispensed by pharmacies that have become certified to dispense. TURALIO will not be available to all pharmacies. To become certified, the pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.

For a pharmacy to become certified, the Authorized Representative must complete the following steps:

Step 1:	Review the Program Overview (this document)
Step 2:	Complete and submit the Pharmacy Enrollment to the TURALIO REMS

By completing the Pharmacy Enrollment Form, the Authorized Representative agrees that:

- I have reviewed the **Program Overview**.
- I must complete the **Pharmacy Enrollment Form** and submit it to the TURALIO REMS.
- I agree to train all relevant staff involved in dispensing TURALIO using the **Program Overview**.

Before dispensing I will ensure that all pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the TURALIO REMS to verify the prescriber is certified, and the patient is enrolled and authorized to receive TURALIO.
- Dispense no more than a 30 days supply for each of the first 3 months of treatment.

On behalf of the pharmacy, we will comply with the following TURALIO REMS requirements:

- **Report adverse events of serious and potentially fatal liver injury by submitting the Liver Adverse Event Reporting Form.**
- Not distribute, transfer, loan or sell TURALIO, except to certified dispensers.
- Maintain records documenting staff's completion of training.
- Maintain records that all TURALIO REMS processes and procedures are in place and being followed.
- Maintain and submit dispensing information for all patients.
- Comply with audits carried out by Daiichi Sankyo, Inc. or third party acting on behalf of Daiichi Sankyo, Inc. to ensure that all processes and procedures are in place and are being followed.

If you have any questions about how to obtain TURALIO, call 1-833-TURALIO (1-833-887-2546).



TURALIO REMS Resources

For more information about the TURALIO REMS, visit www.TURALIOREMS.com or call the TURALIO REMS at 1-833-TURALIO (1-833-887-2546).

The below resources are available for download at www.TURALIOREMS.com.

PRESCRIBER	<ul style="list-style-type: none">• Prescribing Information• Letter for Healthcare Providers and 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
PHARMACY	<ul style="list-style-type: none">• Program Overview• Pharmacy Enrollment Form• Liver Adverse Event Reporting Form
PATIENT	<ul style="list-style-type: none">• Medication Guide• Patient Guide

Please see Prescribing Information for complete safety profile of TURALIO.



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