

# TURALIO REMS



## PATIENT GUIDE

### What is TURALIO™?

TURALIO™ is a prescription medicine used to treat certain adults who have tenosynovial giant cell tumor (TGCT) that is not likely to improve with surgery. TGCT is also known as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS).

### What are the serious risks of TURALIO?

TURALIO can cause serious liver problems, which may be severe and can lead to death.

Stop taking TURALIO and call your healthcare provider right away if you develop:

- yellowing of your skin and whites of your eyes
- dark urine

Tell your healthcare provider right away if you experience:

- lack or loss of appetite
- right upper stomach-area (abdomen) pain or tenderness
- feeling overly tired
- nausea
- vomiting
- fever
- rash
- itching

Liver problems can occur at any time after starting treatment with TURALIO.

These are not all the side effects of TURALIO.

**See the Medication Guide that comes with your prescription for more information.**

### What do I need to do before and while taking TURALIO?

To receive TURALIO, your healthcare provider will provide you with the **Patient Guide** (this document) and discuss the risk of serious liver problems, frequency of blood tests, and symptoms of liver problems with you.

You must enroll in the TURALIO REMS and Patient Registry by completing the **Patient Enrollment Form** with your healthcare provider. The registry collects information so that your health and any liver injury can be followed over time.

It is important that you have a blood test to check your liver health before you start and while you are taking TURALIO.

Your healthcare provider will do blood tests to check for liver problems:

- before starting treatment with TURALIO
- every week for the first 8 weeks during treatment,
- every 2 weeks for the next month,
- then, every 3 months after that

*Please refer to the Medication Guide for more information about TURALIO.*

If you develop liver problems during treatment with TURALIO, your healthcare provider may do blood tests more often to monitor you for serious liver problems.

If you do not have these blood tests, you may no longer be able to receive TURALIO.

You or your family members should tell your healthcare provider right away if you have any symptoms of liver problems while taking TURALIO, even if they begin later in treatment. Liver problems can occur at any time after starting treatment with TURALIO.

## What is a Risk Evaluation and Mitigation Strategy (REMS)?

A REMS is a safety program that the US Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and prescribers must take extra steps to make sure the benefits of using the drug are more than the risks.

## Why does TURALIO Have a REMS?

TURALIO has a REMS because it can cause serious liver problems, which may be severe and can lead to death. The TURALIO REMS was set up to make sure healthcare providers, pharmacists and patients are aware of the serious risks. You must have blood tests to test for liver problems as part of the TURALIO REMS.

TURALIO is available only through healthcare providers and pharmacies that participate in the TURALIO REMS.

## How will I get my TURALIO medicine?

Only certain pharmacies can fill your TURALIO prescription.

The pharmacies that are part of the TURALIO REMS will contact you to fill your prescription for TURALIO and ship it to your home.

If you have questions about the TURALIO REMS, you can call the TURALIO REMS.

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

Hours of Operation: 8:00 AM – 8:00 PM Eastern

[www.TURALIOREMS.com](http://www.TURALIOREMS.com)

## IMPORTANT SAFETY INFORMATION:

If you have any questions about your health or medicines, talk to your healthcare provider.

To report side effects,  
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  
1-800-FDA-1088 or  
[www.fda.gov/medwatch](http://www.fda.gov/medwatch).



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