Treatment with TURALIO

# A guide for people with TGCT

Person depicted is not an actual patient.

## 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). It is not known if TURALIO is safe and effective in children.

## IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about TURALIO® (pexidartinib)?

**TURALIO can cause serious side effects, including serious liver problems, which may be severe and can lead to death, including liver failure and a liver injury called vanishing bile duct syndrome (VBDS) that can cause the loss of bile ducts in the liver. Severe or life-threatening liver problems can happen with TURALIO even if your healthcare provider monitors liver blood tests during treatment and stops treatment with 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 see additional Important Safety Information throughout and Full Prescribing Information, including Boxed WARNING, and Medication Guide.**

Turalio®
pexidartinib
125 mg capsules

# Learning about TURALIO

## Why TURALIO? How might it help?

- TURALIO is a prescription oral treatment for certain adults who have tenosynovial giant cell tumor (TGCT) that is not likely to improve with surgery. TGCT is sometimes also known as PVNS (pigmented villonodular synovitis) or GCT-TS (giant cell tumor of the tendon sheath)
  - TURALIO works by blocking some of the signals that can cause TGCT
- The effectiveness and safety of TURALIO were studied in a controlled trial of 120 people with TGCT who were not candidates for surgery
- The study found that TURALIO reduced tumor size in many patients
- There is important information about the risk of serious liver injury and how to take TURALIO that you should understand before you begin taking it

## What is the most important information I should know about TURALIO? (CONT. See also front cover)

- If you develop liver problems during treatment with TURALIO, your healthcare provider may do blood tests more often to monitor you or refer you to a liver specialist (hepatologist).
- It is important to stay under the care of your healthcare provider during treatment with TURALIO.
- Stop taking TURALIO and call your healthcare provider right away if you develop yellowing of your skin and whites of your eyes or dark urine.
- Tell your healthcare provider right away if you have any of these symptoms of liver problems during treatment with TURALIO: lack or loss of appetite, right upper stomach-area (abdomen) pain or tenderness, feeling overly tired, nausea, vomiting, fever, rash, or itching.

## TURALIO Risk Evaluation and Mitigation Strategy (REMS)

- Because of the risk of serious liver problems, TURALIO is available only through a restricted program called the TURALIO REMS Program.
- Your healthcare provider must be enrolled in the program in order for you to be prescribed TURALIO.
- There is a registry that collects information about the effects of taking TURALIO over time.
- You must complete and sign an enrollment form for the TURALIO REMS Program and the registry.

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# How was TURALIO studied?

## TURALIO was studied in a large clinical trial

- TURALIO was studied in the first clinical trial of an oral treatment for TGCT
- The trial included 120 people who had advanced TGCT for whom surgery was not recommended
- For 24 weeks, half of the people in the trial took TURALIO and half took a placebo. After 24 weeks, people in both groups were offered TURALIO as longer-term treatment
- The study also collected information on the safety of TURALIO

## The study tested whether TURALIO was able to:

Eliminate or reduce tumor size

Increase joint movement

## Of patients in the trial:

**88%**
(105 of 120 patients) had
**DIFFUSE TGCT AFTER SURGERY**

**47%**
(56 of 120 patients) had
**NO PRIOR SURGERY FOR TGCT**

Person depicted is not an actual patient.

**Please see additional Important Safety Information throughout and Full Prescribing Information, including Boxed WARNING, and Medication Guide.**

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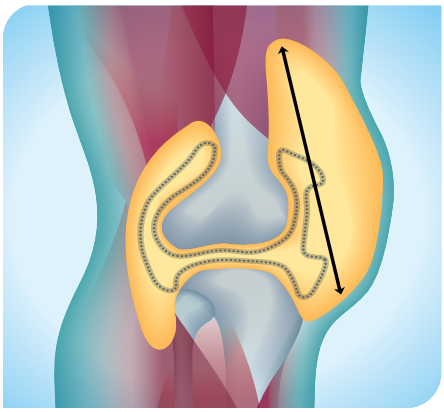
# Clinical trial results

## TURALIO helped reduce tumor size at 25 weeks

Tumor size was measured in 2 ways.

The first measurement was the **LENGTH** of the tumor.



**at 25 weeks**

**38%** of patients (23 out of 61) receiving TURALIO

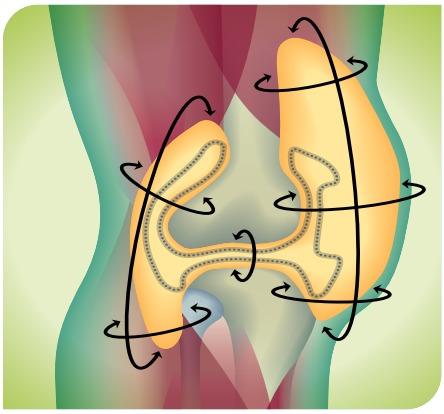
HAD A RESPONSE IN TUMOR

**LENGTH**

Of the people taking TURALIO:

- 23% (14 out of 61) had their tumors reduce in length by 30% or more
- 15% (9 out of 61) had their tumors disappear completely[a]

The second measurement was the **VOLUME** of the tumor.



**at 25 weeks**

**56%** of patients (34 out of 61) receiving TURALIO

HAD A RESPONSE IN TUMOR

**VOLUME**

Of the people taking TURALIO:

- 51% (31 out of 61) had their tumors reduce in volume by 50% or more
- 5% (3 out of 61) had their tumors disappear completely[a]
- People who responded to TURALIO responded for a range of 6.9+ to 24.0+ months

+ indicates that the response is ongoing at last assessment.

None of the people taking placebo experienced a reduction in tumor length or volume.

[a]Complete response was defined as 100% reduction in tumor length or volume.

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# Clinical trial results (CONT.)

## Responses improved with time

At completion of the clinical trial

**at ~5.5 years**

**61%** of patients (37 out of 61) receiving TURALIO

HAD A RESPONSE IN TUMOR LENGTH

The median duration of response was not reached in the 37 responders.

### IMPORTANT SAFETY INFORMATION (CONT.)

**Before you take TURALIO, tell your healthcare provider about all of your medical conditions,** including if you have or had liver or kidney problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. TURALIO may harm your baby. Do not breastfeed during treatment with TURALIO and for at least 1 week after your final dose.

- **If you are a female who is able to become pregnant**, your healthcare provider will do a pregnancy test before you start treatment with TURALIO. You should use an effective non-hormonal method of birth control (contraception) during treatment with TURALIO and for 1 month after your final dose of TURALIO. Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective if used during treatment with TURALIO. Talk with your healthcare provider about birth control methods you can use during this time. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with TURALIO.
- **If you are a male with a female partner who is able to become pregnant**, use effective birth control (contraception) during treatment and for 1 week after your final dose of TURALIO. Tell your healthcare provider right away if your female partner becomes pregnant or thinks she is pregnant during your treatment with TURALIO.

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# More clinical trial results

## People taking TURALIO had significantly improved range of motion compared to patients taking placebo at 25 weeks

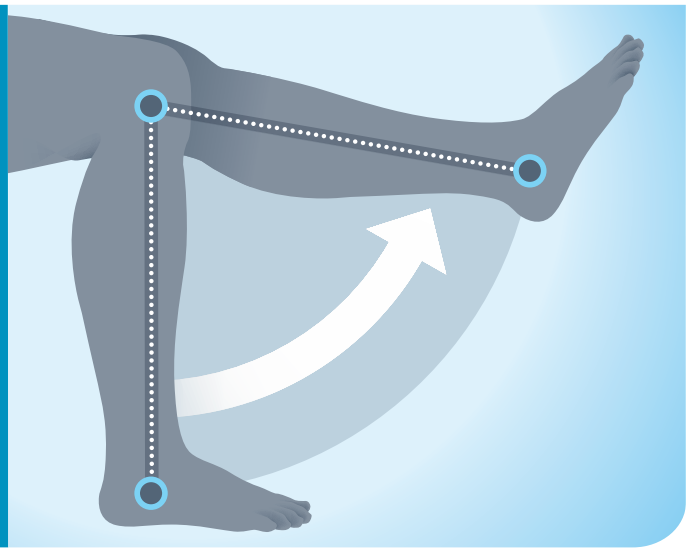
- Range of motion (ROM) is a measure of the amount of movement possible in a specific joint

**Mean ROM in patients taking TURALIO at the start of the study was 62.5%. With TURALIO treatment, ROM had improved 15.1% to about 77% of possible movement for the joint. Patients taking placebo had a 62.9% mean ROM at the start of the study and experienced an increase of 6.2% in ROM**

Information on range of motion was not available for 16 of 61 patients taking TURALIO and for 16 of 59 patients taking placebo. It was not possible to know if the people with data missing were experiencing worse range of motion than people with data available.

### WHAT IS RANGE OF MOTION?

Range of motion is a measure of the amount of movement possible in a specific joint.



Individual responses may vary.

### IMPORTANT SAFETY INFORMATION (CONT.)

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the way TURALIO works and TURALIO may affect how other medicines work. **Taking TURALIO with certain medicines may increase the amount of TURALIO in your blood. This may make it more likely for you to have side effects and may cause more severe side effects.** Avoid taking proton pump inhibitor medicines and St. John's wort because they can affect how TURALIO works. If you take an antacid medicine, take TURALIO either **2 hours before or 2 hours after** taking an antacid medicine. If you take an $H_2$ receptor blocker medicine, take TURALIO **at least 2 hours before or 10 hours after** taking an $H_2$ receptor blocker medicine.

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**Ask your healthcare provider for more information.**

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# Dosing and dosing schedule

## How should I take TURALIO?

Your healthcare provider will explain how you will receive your TURALIO. Take TURALIO exactly as your healthcare provider tells you to. TURALIO is usually taken 2 times a day. You might find it helpful to take TURALIO at the same time each day. Your healthcare provider will tell you how much TURALIO to take and when to take it.

**Remember:**

- **Take TURALIO with a low-fat meal (approximately 11 to 14 grams of total fat). Taking TURALIO with a high-fat meal (about 55 to 65 grams of total fat) increases the amount of TURALIO in your blood. This may make it more likely for you to develop side effects and may cause more severe side effects, including serious liver problems.**
- **Please see additional Important Safety Information on pages 1-2 about "What is the most important information I should know about TURALIO?" and enclosed Medication Guide.**

**Talk with your healthcare provider about examples of foods that you can eat for a low-fat meal that contains about 11 to 14 grams of total fat.** Your healthcare provider may refer you to a dietitian, if needed.

When taking TURALIO:

- It's important to swallow the capsules whole. Do not open, break, or chew them
- If you vomit or miss a dose of TURALIO, take the next dose at its scheduled time

Call your doctor if you have questions about dosing, side effects, or how long to continue treatment.

**The recommended dosage of TURALIO is 250 mg (2 x 125 mg) taken orally twice daily for a maximum dose of 500 mg per day. TURALIO 125 mg capsules must be taken with a low-fat meal that contains about 11 to 14 grams of total fat.**

Take your medication
WITH A
**LOW-FAT MEAL**
(about 11-14 grams of total fat)

**Please see additional Important Safety Information throughout and Full Prescribing Information, including Boxed WARNING, and Medication Guide.**

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# Important Safety Information

## What should I avoid while taking TURALIO?

- **Avoid taking TURALIO with a high-fat meal (about 55 to 65 grams of total fat).** Taking TURALIO with a high-fat meal increases the amount of TURALIO in your blood. This may make it more likely for you to develop side effects and may cause more severe side effects, including serious liver problems.
- **Avoid grapefruit or drinking grapefruit juice during treatment with TURALIO.** Grapefruit or grapefruit juice can cause you to have too much TURALIO in your blood and may lead to increased side effects and more severe side effects.
- **Avoid spending prolonged time in sunlight.** TURALIO can make your skin sensitive to the sun (photosensitivity), and you may burn more easily. You should use sunscreen and wear protective clothing that covers your skin to help protect against sunburn if you have to be in the sunlight during treatment with TURALIO.

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# More safety information about TURALIO

## The most common side effects of TURALIO include:

Changes in blood liver tests

Hair color changes

- About 67% (41 of 61) of patients treated with TURALIO in the clinical trial had hair color changes
- Hair dye may be used during treatment with TURALIO to achieve your preferred shade

Tiredness

Increased cholesterol level in the blood

Decreased white blood cells and red blood cells

Swelling in or around your eyes

Rash, itching, hives, skin redness, and acne

Loss of taste or changes in the way things taste

Decreased phosphate in your blood

TURALIO may affect fertility in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility

These are not all of the possible side effects of TURALIO.
Call your doctor for medical advice about side effects

**You are encouraged to report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

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# Talking with your healthcare provider about TURALIO

Before starting TURALIO, make sure you understand how to take it (with a low-fat meal) and when you need to call your healthcare provider's office. This list of questions may be helpful as you discuss TURALIO with your healthcare provider.

| | ✓ |
|---|---|
| Have I provided my healthcare team with a list of all of the medicines I take, including over-the-counter medicines and nutritional supplements? | |
| Do I understand the importance of taking TURALIO with a low-fat meal? | |
| When should I call the healthcare provider's office? | |
| How will my progress be measured? | |
| What side effects might I have with TURALIO? What happens if I have side effects? | |
| What else do I need to know about the safety of TURALIO? | |
| How often do I need to have lab work done? | |
| When do I need to see the healthcare provider again? | |

## Special instructions from my healthcare provider

## Questions for my next healthcare provider visit

**Please see additional Important Safety Information throughout and Full Prescribing Information, including Boxed WARNING, and Medication Guide.**

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# Taking TURALIO quick reference

**Please work with your doctor to fill in your personal dosing information**

## Dosing instructions

- Your dose is _____ mg (___ 125-mg capsules) taken ____ times a day
- TURALIO must be taken with a **low-fat meal** (about 11 to 14 grams of total fat)
- It's important to **swallow the capsules whole.** Do not open, break, or chew them
- If you vomit or miss a dose of TURALIO, take the next dose at its scheduled time

## What should I avoid while taking TURALIO?

- **Avoid taking TURALIO with a high-fat meal (about 55 to 65 grams of total fat).** Taking TURALIO with a high-fat meal increases the amount of TURALIO in your blood. This may make it more likely for you to develop side effects and may cause more severe side effects, including serious liver problems.
- **Avoid grapefruit or drinking grapefruit juice during treatment with TURALIO.** Grapefruit or grapefruit juice can cause you to have too much TURALIO in your blood and may lead to increased side effects and more severe side effects.
- **Avoid spending prolonged time in sunlight.** TURALIO can make your skin sensitive to the sun (photosensitivity), and you may burn more easily. You should use sunscreen and wear protective clothing that covers your skin to help protect against sunburn if you have to be in the sunlight during treatment with TURALIO.

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# When to call the office

Call the office at _____ if you think you may be experiencing a side effect, or are considering taking any medicines (including over-the-counter medicines) or nutritional supplements

STOP

**Stop taking TURALIO** and call your healthcare provider right away if you develop yellowing of your skin and whites of your eyes or dark urine.

Tell your healthcare provider right away if you have any of these symptoms of liver problems during treatment with TURALIO: lack or loss of appetite, right upper stomach-area (abdomen) pain or tenderness, feeling overly tired, nausea, vomiting, fever, rash, or itching.

# Tracking appointments

You will have regular office visits and blood testing under the Risk Evaluation and Mitigation Strategy (REMS) program.

Keep track of your appointments by writing down the dates for your required blood tests[a]:

| Week 1 | Week 2 | Week 3 | Week 4 |
|---|---|---|---|
| | | | |

| Week 5 | Week 6 | Week 7 | Week 8 |
|---|---|---|---|
| | | | |

| Week 10 | Week 12 |
|---|---|
| | |

| 6 Months | 9 Months |
|---|---|
| | |

[a]After 8 weeks, testing is done every 2 weeks. After you've been treated with TURALIO for 12 weeks, you'll have blood tests every 3 months. If a problem is noted, your healthcare provider may decide to test more frequently.

Keep track of any other follow-up appointments with your doctor:

| | | | |
|---|---|---|---|
| | | | |

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# Indication and Important Safety Information

## 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). It is not known if TURALIO is safe and effective in children.

## IMPORTANT SAFETY INFORMATION

**What is the most important information I should know about TURALIO® (pexidartinib)? TURALIO can cause serious side effects, including serious liver problems, which may be severe and can lead to death, including liver failure and a liver injury called vanishing bile duct syndrome (VBDS) that can cause the loss of bile ducts in the liver. Severe or life-threatening liver problems can happen with TURALIO even if your healthcare provider monitors liver blood tests during treatment and stops treatment with 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.

- If you develop liver problems during treatment with TURALIO, your healthcare provider may do blood tests more often to monitor you or refer you to a liver specialist (hepatologist). It is important to stay under the care of your healthcare provider during treatment with TURALIO. Stop taking TURALIO and call your healthcare provider right away if you develop yellowing of your skin and whites of your eyes or dark urine. Tell your healthcare provider right away if you have any of these symptoms of liver problems during treatment with TURALIO: lack or loss of appetite, right upper stomach-area (abdomen) pain or tenderness, feeling overly tired, nausea, vomiting, fever, rash, or itching.
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**Before you take TURALIO, tell your healthcare provider about all of your medical conditions,** including if you have or had liver or kidney problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. TURALIO may harm your baby. Do not breastfeed during treatment with TURALIO and for at least 1 week after your final dose.

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# Indication and Important Safety Information (CONT.)

- **If you are a male with a female partner who is able to become pregnant**, use effective birth control (contraception) during treatment and for 1 week after your final dose of TURALIO. Tell your healthcare provider right away if your female partner becomes pregnant or thinks she is pregnant during your treatment with TURALIO.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the way TURALIO works and TURALIO may affect how other medicines work. **Taking TURALIO with certain medicines may increase the amount of TURALIO in your blood. This may make it more likely for you to have side effects and may cause more severe side effects.** Avoid taking proton pump inhibitor medicines and St. John's wort because they can affect how TURALIO works. If you take an antacid medicine, take TURALIO either **2 hours before or 2 hours after** taking an antacid medicine. If you take an $H_2$ receptor blocker medicine, take TURALIO **at least 2 hours before or 10 hours after** taking an $H_2$ receptor blocker medicine.

**Take TURALIO with a low-fat meal (about 11 to 14 grams of total fat).** See "What should I avoid while taking TURALIO?" TURALIO capsules must be swallowed whole. Do not open, break, or chew TURALIO capsules.

### What should I avoid while taking TURALIO?

- **Avoid taking TURALIO with a high-fat meal (about 55 to 65 grams of total fat).** Taking TURALIO with a high-fat meal increases the amount of TURALIO in your blood. This may make it more likely for you to develop side effects and may cause more severe side effects, including serious liver problems.
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- **Avoid spending prolonged time in sunlight.** TURALIO can make your skin sensitive to the sun (photosensitivity), and you may burn more easily. You should use sunscreen and wear protective clothing that covers your skin to help protect against sunburn if you have to be in the sunlight during treatment with TURALIO.

### What are the most common side effects of TURALIO?

The most common side effects of TURALIO include changes in blood liver tests; hair color changes; tiredness; increased cholesterol level in the blood; decreased white blood cells and red blood cells; swelling in or around your eyes; rash, itching, hives, skin redness, and acne; loss of taste or changes in the way things taste; and decreased phosphate in your blood.

**Please see additional Important Safety Information throughout and Full Prescribing Information, including Boxed WARNING, and Medication Guide.**

# Indication and Important Safety Information (CONT.)

TURALIO may affect fertility in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

**These are not all of the possible side effects of TURALIO. Call your doctor for medical advice about side effects. You are encouraged to report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Please see Medication Guide, including Important Warning.

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Daiichi-Sankyo | access central™

# A single source for TURALIO patient support

While other people may be on the same medication as you, every patient who receives a TURALIO prescription has different and unique circumstances. Daiichi Sankyo Access Central coordinators are here to help you again access the medication, support and information you need to start and continue your treatment journey. They will provide information about accessing your medication and you can get answers to frequently asked questions about health insurance.

Learn how to get your medication and find additional support by calling Biologics at **1-800-850-4306**.

## TURALIO Copay Program[a]

Commercially insured patients may pay as little as $0 per prescription

[a] Terms and conditions apply. Terms, conditions, and eligibility requirements can be found online at **DSIAccessCentral.com/patient/TURALIO**.

## TURALIO Patient Assistance Program

This program may provide your medication at no cost for financially-eligible patients who are uninsured or underinsured

## TURALIO QuickStart Program

14-day prescription at no cost for eligible patients

Learn more about TURALIO at **TURALIO.com**.

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