

Medication Guide
TURALIO® (tur-a-lee-oh)
(pexidartinib)
capsules

What is the most important information I should know about TURALIO?

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
- 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
- vomiting
- right upper stomach-area (abdomen) pain or tenderness
- fever
- feeling overly tired
- rash
- nausea
- 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. Ask your healthcare provider for more information.

See “What are the possible side effects of TURALIO?” for more information about side effects.

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.

Before taking TURALIO, tell your healthcare provider about all of your medical conditions, including if you:

- have or had liver problems.
- have kidney problems.
- are pregnant or plan to become pregnant. TURALIO may harm your unborn baby.

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.
- Females who are able to become pregnant should use effective non-hormonal 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.
- are breastfeeding or plan to breastfeed. **Do not** breastfeed during treatment with TURALIO and for at least 1 week after your final dose of 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 develop side effects and may cause more severe side effects.

- Avoid taking the following medicines or supplements during treatment with TURALIO because they can affect how TURALIO works:
 - Proton Pump Inhibitor medicines (PPIs)
 - St. John’s wort

How should I take TURALIO?

- **Your healthcare provider will explain to you how you will receive your TURALIO.**
- Take TURALIO exactly as your healthcare provider tells you to.
- TURALIO is usually taken 2 times a day. Your healthcare provider will tell you how much TURALIO to take and when to take it.
- **Take TURALIO with a low-fat meal (about 11 to 14 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. See “What are the possible side effects of TURALIO?”**
 - **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 dietician, if needed.
- Swallow TURALIO capsules whole.
- **Do not** open, break, or chew TURALIO capsules.
- If you need to take an acid-reducing medicine, follow your healthcare provider’s instructions for which medicine to take and when to take it.
 - If you take an antacid medicine: Take TURALIO either **2 hours before or 2 hours after** taking an antacid medicine.
 - If you take an H₂ receptor blocker medicine: Take TURALIO **at least 2 hours before or 10 hours after** taking an H₂ receptor blocker medicine.
- **Tell your healthcare provider about all the medicines you take. See the section “Before taking TURALIO, tell your healthcare provider about all of your medical conditions, including if you:”**
- If you vomit after taking a dose, or if you miss a dose of TURALIO, take your next dose at your regular time.

What should I avoid while taking TURALIO?

- 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.

What are the possible side effects of TURALIO?

TURALIO can cause serious side effects.

- See “**What is the most important information I should know about TURALIO?**”
- **There are possible risks if TURALIO is taken with a high-fat meal. 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 medicine 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. **Take TURALIO with a low-fat meal (about 11 to 14 grams of total fat).** See “**How should I take TURALIO?**”

The most common side effects of TURALIO include:

- changes in blood liver tests
- hair color changes
- tiredness
- increased cholesterol level in your 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 may report side effects to FDA at 1-800-FDA-1088.

How should I store TURALIO?

- Store TURALIO at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the TURALIO container closed tightly.
- TURALIO comes with a drying agent (desiccant) in the container. Keep the desiccant in the container.

Keep TURALIO and all medicines out of the reach of children.

General information about the safe and effective use of TURALIO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TURALIO for a condition for which it was not prescribed. Do not give TURALIO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TURALIO that is written for health professionals.

What are the ingredients in TURALIO?

Active Ingredient: pexidartinib

Inactive Ingredients: poloxamer 407, mannitol, crospovidone, and magnesium stearate. Capsule shell: hypromellose, titanium dioxide, and FD&C Blue No. 1

Manufactured for: Daiichi Sankyo, Inc., Basking Ridge, NJ 07920

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For more information, call 1-877-437-7763 or go to <https://www.turalio.com>.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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