

Repotrectinib (Augtyro)

About This Medicine

REPOTRECTINIB (RE poe TREK ti nib) treats lung cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Constipation (not able to move bowels)
- Nausea
- Changes in the way food and drinks taste
- Effects on the nerves are called peripheral neuropathy. You may feel numbness, tingling, or pain in your hands and feet. It may be hard for you to button your clothes, open jars, or walk as usual. The effect on the nerves may get worse with more doses of the medicine. These effects get better in some people after the medicine is stopped but it does not get better in all people.
- Tiredness
- Feeling dizzy
- Loss of balance or coordination
- Problems with thinking, such as forgetfulness, confusion, problems with concentration or attention, memory problems and hallucinations (see or hear things that are not there)
- Muscle weakness (lack of muscle strength)
- Trouble breathing

Note: Each of the side effects above was reported in 20% or greater of people treated with repotrectinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel dizzy, have hallucinations, have trouble thinking such as confusion or forgetfulness, changes in mood such as feeling nervous or worried (anxiety), irritability,



depression. You could have problems with concentration, attention, sleep and/or a loss of balance or coordination.

- Inflammation (swelling) and/or scarring of the lungs. You may have a cough and/or trouble breathing
- Changes in your liver function
- Muscle pain with or without an increase in creatine phosphokinase (CPK), which can sometimes be the result of muscle inflammation or damage. You may have muscle aching and/or cramping.
- Increased uric acid in the blood
- Risk of bone fractures

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

Important Information

- This medicine may impair your ability to drive or use machinery. Use caution and talk to your care team about any precautions you may need to take.

How to Take Your Medicine

- Swallow the medicine whole with or without food, at approximately the same time each day. Do not open, chew, crush or dissolve the capsules.
- If any of the capsules are broken, do not touch them with bare hands. Carefully throw away the capsules and wash your hands after handling.
- Missed dose: If you vomit or miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- Handling: Wash your hands with soap and water before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- Storage: Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- Disposal of unused medicine: Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- Drink enough fluids to keep your urine pale yellow.



- If you throw up, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicines that are available to help stop or lessen constipation.
- Taking good care of your mouth may help food taste better and improve your appetite.
- Manage tiredness by pacing your activities for the day.
- If you are dizzy, get up slowly after sitting or lying.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of repotrectinib in your body which could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with repotrectinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.
- This medicine interacts with hormonal birth control (i.e., birth control pills, skin patches, vaginal rings, injections) and affect how they work. Discuss with your care team what method of birth control may be right for you during your treatment.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Blurry vision or other changes in eyesight
- Feeling dizzy or lightheaded
- Tiredness and/or weakness that interferes with your daily activities
- Trouble thinking and/or memory loss



- Trouble with concentration and/or attention
- Feel irritable, nervous, or restless
- Hallucinations
- Confusion or forgetfulness
- Trouble falling or staying asleep
- Loss of balance or coordination
- Pain in your chest
- Dry cough
- Wheezing and/or trouble breathing
- Changes in the way food and drink taste that is causing a loss of appetite
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- No bowel movement in 3 days or when you feel uncomfortable
- Pain in your abdomen and/or flank area that does not go away
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Unexplained muscle pain, tenderness, or weakness
- Numbness, tingling, or pain in your hands and feet
- Warm, red, tender or swollen joints, especially in your big toe
- Pain that does not go away, or is not relieved by prescribed medicines
- Decreased or very dark urine
- Urine that is pink or brownish in color

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use non-hormonal birth control while taking this medicine and for 2 months after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 4 months after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective with this medicine.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 10 days after the last dose.
- **Fertility warning:** The effect of this medicine on fertility is not known. If you plan to have children, talk with your care team.

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