

Repotrectinib (Augtyro)

About This Medicine

Repotrectinib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Constipation (not able to move bowels)
- Feeling dizzy
- 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.
- Trouble breathing
- Tiredness
- 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)

Note: Each of the side effects above was reported in 20% or greater of patients 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 medical 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 medical team.

Important Information

- This medicine may impair your ability to drive or use machinery. Use caution and talk to your doctor and/or nurse 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.
- **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.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature.
- **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 nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Drink enough fluids to keep your urine pale yellow.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Ask your doctor or nurse 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 doctor'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 doctor or nurse 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 doctor or pharmacist 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 doctor or pharmacist 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 doctor and/or nurse what method of birth control may be right for you during your treatment.

When to Call the Doctor

Call your doctor or nurse 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
- Red, hot, tender or swollen joints, especially in your big toe
- Pain that does not go away, or is not relieved by prescribed medicines
- Decreased urine or very dark urine
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of non-hormonal birth control during your cancer treatment and for 2 months after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 4 months after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective with this medicine.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 10 days after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Fertility studies have not been done with this medicine. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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