

ORAL CANCER TREATMENT EDUCATION



PASSION FOR PATIENTS
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REPOTRECTINIB

Name of your medication

Generic name — repotrectinib (RE poe TREK tinib)

Brand name — AUGTYRO® (Aug-TYE-ro)

Common uses

Repotrectinib is used to treat non-small cell lung cancer (NSCLC) that has a genetic variant in the *ROS1* gene.

Repotrectinib may also be used for other treatments.

Dose and schedule

Taking repotrectinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of repotrectinib is 160 milligram (160 mg) to be taken by mouth at a scheduled time once a day for 14 days, followed by 160 milligram (160 mg) to be taken by mouth at a scheduled time twice a day.
- Repotrectinib can be taken with or without food, but at the same time each day.
- Repotrectinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow repotrectinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of repotrectinib, do not take an extra dose or two doses at one time. Simply take your next dose at the regularly scheduled time. Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Drug and food interactions

- Repotrectinib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- Grapefruit or grapefruit juice may interact with repotrectinib; avoid eating or drinking these during treatment with repotrectinib.
- Repotrectinib may cause hormonal birth control to be less effective. Talk with your care provider for a safe and effective nonhormonal birth control method.

Storage and handling

Handle repotrectinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store repotrectinib at room temperature (68°F to 77°F) in a dry location away from light.
- Keep repotrectinib out of reach of children and pets.
- Leave repotrectinib in the provided packaging until it is ready to be taken.

ORAL CANCER TREATMENT EDUCATION



PASSION FOR PATIENTS
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REPOTRECTINIB

- Whenever possible, you should give repotrectinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the repotrectinib to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the repotrectinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder will be used, contact your care team before using and follow these guidelines:
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.

Side Effects of Repotrectinib

Below are common side effects that have been known to happen in about one-third or more of patients taking repotrectinib; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Decreased hemoglobin, part of the red blood cells that carry iron and oxygen	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7 to 8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between “work” and “rest.” • Stay as active as possible, but know that it is okay to rest as needed, too. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience the following symptoms:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
Dizziness	<p>You may notice a lightheaded, weak, or unsteady feeling while you are on this medication. Use caution when driving and operating machinery.</p> <p>Let your provider know if this feeling occurs.</p>

Continued on the next page

ORAL CANCER TREATMENT EDUCATION



REPOTRECTINIB

Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • High creatine phosphokinase (CPK) • High gamma-glutamyl transpeptidase (GGT) • High uric acid 	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you experience any of the following:</p> <ul style="list-style-type: none"> • Muscle pain • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red or brown colored urine
<p>Taste changes</p>	<p>Some people experience a metallic or bitter taste in their mouth. To help with taste changes:</p> <ul style="list-style-type: none"> • Choose and prepare foods that look and smell good to you. • Use plastic utensils if food tastes like metal. • Flavor foods with spices to change taste. • Suck on mints or chew gum to mask taste. • Brush teeth before and after eating with a soft bristle toothbrush. • Avoid smoking. <p>Notify your doctor if you are having trouble eating or are losing weight.</p>
<p>Numbness or tingling in hands or feet</p>	<p>Report changes in your sense of touch, such as a burning sensation, pain on the skin, or weakness, to your care provider.</p>
<p>Changes in liver function</p>	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following symptoms:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising

Continued on the next page

ORAL CANCER TREATMENT EDUCATION



PASSION FOR PATIENTS
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REPOTRECTINIB

Possible Side Effect	Management
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infections. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any of the following signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
<p>Constipation</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8-10 glasses of water/fluid each day unless your care provider has instructed you to limit your fluid intake. • Stay active and exercise, if possible. • Eat foods high in fiber like raw fruits and vegetables. <p>Contact your care provider if you have not had a bowel movement in 3 or more days.</p> <p>Your care provider may recommend over-the-counter medications to help with your constipation. A daily stool softener such as docusate (Colace®) and/or laxative such as senna (Senakot®) may be helpful. If these do not help within 48 hours, tell your provider</p>
<p>Cough or shortness of breath</p>	<p>A cough that does not produce any mucous or congestion relief (i.e., dry cough) may occur while taking this medication. If you experience any breathing problems or shortness of breath, notify your care provider immediately. This may be a serious side effect of the medication.</p>

ORAL CANCER TREATMENT EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



REPOTRECTINIB

Serious side effects

- Repotrectinib can cause central nervous system toxicity. You may feel more tired than normal. Repotrectinib may also cause vertigo, which is a condition where you may feel like you are spinning or that the inside of your head is spinning. Speak with your care team if you notice any of these symptoms.
- Repotrectinib may cause interstitial lung disease, which causes your lungs to scar. Call your care team if you are feeling short of breath, have a fever, or have a lasting dry cough.
- Repotrectinib can cause bones and muscles to weaken and may increase your risk for falls and broken bones. Your doctor may prescribe a medication to decrease your risk of broken bones.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Because repotrectinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take repotrectinib, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems:
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or repotrectinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking repotrectinib.
 - Females of childbearing age and potential should use effective nonhormonal contraception during therapy and for a minimum of 2 months after the last dose of repotrectinib.
 - Males with female partners of childbearing potential should use effective contraception during therapy and for a minimum of 4 months after the last dose of repotrectinib.

ORAL CANCER TREATMENT EDUCATION



PASSION FOR PATIENTS
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REPOTRECTINIB

- ❑ Repotrectinib may cause hormonal contraceptives to be ineffective. Effective contraception while taking repotrectinib should be nonhormonal and may include 1 or more of the following: barrier methods, copper intrauterine device (IUD), etc. Speak with your care provider if you are unsure of effective nonhormonal contraception.
- ❑ Do not breastfeed while taking repotrectinib and for 10 days after the last dose of repotrectinib.
- ❑ Please inform your care provider if you become pregnant.
- ❑ It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care team for assistance.

Obtaining medication

- ❑ Talk with your care provider about the process for obtaining your repotrectinib.

(PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.augtyro.com>

Product prescribing information: https://packageinserts.bms.com/pi/pi_augtyro.pdf

Product resources: <https://www.augtyro.com/education-and-support>

Updated – February 5, 2024

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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