

**PATIENT INFORMATION**  
**AUGTYRO™ [Aug-TYE-ro]**  
**(repotrectinib)**  
**capsules**

**What is the most important information I should know about AUGTYRO?**

**AUGTYRO may cause serious side effects, including:**

- **Central nervous system (CNS) effects.** Tell your healthcare provider right away if you experience any new or worsening symptoms of CNS effects during treatment with AUGTYRO, including:
  - dizziness
  - vertigo
  - changes in mood, such as anxiety, irritability, and depression
  - balance or coordination problems
  - problems with thinking, such as forgetfulness or confusion
  - seeing or hearing things that are not real (hallucinations)
  - problems with concentration, attention, memory, and sleep
- **Lung problems (pneumonitis).** Tell your healthcare provider if you have any new or worsening symptoms of lung problems, including a dry cough (without mucus), productive cough (with mucus), wheezing, or trouble breathing.
- **Liver problems.** Your healthcare provider will do blood tests to check your liver function before starting and during treatment with AUGTYRO. Tell your healthcare provider right away if you develop symptoms of liver problems including:
  - your skin or the white part of your eyes turns yellow
  - dark or “tea-colored” urine
  - light-colored stools (bowel movements)
  - loss of appetite
  - nausea or vomiting
  - pain on the upper right side of your stomach area
- **Muscle problems.** Your healthcare provider will do blood tests before starting treatment with AUGTYRO, at least every 2 weeks for the first month and as needed during treatment. Tell your healthcare provider right away if you get new or worsening signs and symptoms of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.
- **Increased uric acid level in your blood (hyperuricemia).** AUGTYRO may cause an excess of uric acid in your blood. Your healthcare provider will do tests before and during your treatment with AUGTYRO to check the uric acid level in your blood. Your healthcare provider may prescribe medications if you have high blood uric acid levels. Tell your healthcare provider if you experience symptoms of increased uric acid including:
  - red, hot, tender, or swollen joints, especially in your big toe
  - pain in your stomach-area or sides
  - decrease in your amount of urine or no urine at all
  - nausea or vomiting
  - pink or brown urine or blood in your urine
- **Bone fractures.** AUGTYRO may increase your risk for bone fractures. Bone fractures may happen with or without a fall or other injury. Tell your healthcare provider right way if you have pain, changes in movement, or bone abnormalities.

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

**What is AUGTYRO?**

AUGTYRO is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that has spread within your chest or to other parts of the body and is caused by an abnormal *ROS1* gene.

It is not known if AUGTYRO is safe and effective in children.

**Before taking AUGTYRO, tell your healthcare provider about all your medical conditions, including if you:**

- have nervous system (neurological) problems.
- have lung or breathing problems other than lung cancer.
- have liver problems.
- are pregnant or plan to become pregnant. AUGTYRO can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with AUGTYRO.

**Females who are able to become pregnant:**

- Your healthcare provider should do a pregnancy test before you start treatment with AUGTYRO.
- You should use effective non-hormonal birth control (contraception) during treatment and for 2 months after the last dose of AUGTYRO.
- Birth control methods that contain hormones (such as birth control pills, injections or transdermal system patches) may not work as well during treatment with AUGTYRO.
- Talk to your healthcare provider about birth control methods that may be right for you.

**Males with female partners who are able to become pregnant:**

- You should use effective birth control during treatment with AUGTYRO and for 4 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if AUGTYRO passes into your breast milk. Do not breastfeed during treatment and for 10 days after the last dose of AUGTYRO. Talk to your healthcare provider about the best way to feed your baby during this time.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

**How should I take AUGTYRO?**

- Take AUGTYRO exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking AUGTYRO unless your healthcare provider tells you to.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with AUGTYRO if you develop side effects.
- Take AUGTYRO at about the same time each day with or without food.
- Swallow AUGTYRO capsules whole with water. Do not open, crush, chew or dissolve the capsule. Do not take a capsule if it is broken, cracked, or damaged.
- If you miss a dose, or vomit at any time after taking a dose of AUGTYRO, do not take an extra dose. Just skip the dose and take your next dose at the regularly scheduled time. Do not take 2 doses at the same time to make up a missed or vomited dose.

**What should I avoid while taking AUGTYRO?**

- You should not drink grapefruit juice or eat grapefruit during your treatment with AUGTYRO. It may increase the amount of AUGTYRO in your blood to a harmful level.
- Do not drive or operate machinery until you know how AUGTYRO affects you. If you experience dizziness, blurred vision, memory loss, changes in mental status, confusion, hallucinations or have trouble with balance or coordination or problems with concentration and attention, do not drive or operate machinery until your symptoms have resolved.

**What are the possible side effects of AUGTYRO?**

**AUGTYRO may cause serious side effects, including:**

- See “**What is the most important information I should know about AUGTYRO?**”

**The most common side effects of AUGTYRO include:**

- |  |  |
|--|--|
| • dizziness  | • shortness of breath  |
| • change in sense of taste                             | • problems with thinking, such as forgetfulness or confusion, memory problems and hallucinations |
| • feeling of numbness or tingling in your arms or legs | • tiredness  |
| • constipation   | • nausea   |
| • trouble with balance, coordination, and walking      |  |

These are not all the possible side effects of AUGTYRO.

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 AUGTYRO?**

- Store AUGTYRO at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep AUGTYRO and all medicines out of the reach of children.**

**General information about the safe and effective use of AUGTYRO.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use AUGTYRO for a condition for which it was not prescribed. Do not give AUGTYRO 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 AUGTYRO that is written for health professionals.

**What are the ingredients of AUGTYRO?**

**Active ingredient:** repotrectinib

**Inactive ingredients:** microcrystalline cellulose, sodium lauryl sulfate, croscarmellose sodium, and colloidal silicon dioxide. Capsule shell contains gelatin and titanium dioxide. Printing ink contains shellac and FD & C blue #2 aluminum lake.

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For more information, go to [www.AUGTYRO.com](http://www.AUGTYRO.com) or call 1-877-284-8976.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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