

### What is AUGTYRO®?

#### INDICATION

AUGTYRO (repotrectinib) 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 with *ROS1*-positive NSCLC.

Talk to your healthcare team for more information about what it means to have an abnormal *ROS1* gene.

AUGTYRO is indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC).

#### **IMPORTANT SAFETY INFORMATION**

AUGTYRO may cause serious side effects, including central nervous system (CNS) effects, lung problems (pneumonitis), liver problems, muscle problems, increased uric acid level in your blood (hyperuricemia), and bone fractures.

### **How to take AUGTYRO**



Days 1-14

For the first 14 days, you will start with a dose of 1 pill of 160 mg a day until your doctor recommends otherwise.



Day 15 and throughout your treatment

On Day 15, you will start taking 1 pill of 160 mg in the morning and 1 pill of 160 mg in the evening every day until your doctor recommends otherwise.

#### A **40-mg dosing** option is also available

#### Remember to take AUGTYRO as your doctor instructs you.



If you miss a dose or vomit at any time after taking a dose of AUGTYRO, do not take an extra dose. 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



AUGTYRO may be taken with or without food

- It should be swallowed whole with water at about the same time each day as prescribed
- Avoid eating grapefruit or drinking grapefruit juice during your treatment with AUGTYRO



Remember not to open, crush, chew, or dissolve the capsule. Do not to take a capsule if it is broken, cracked, or damaged



# Keep these tips in mind to help stay on track with AUGTYRO.



### Take AUGTYRO as directed.

As with any medicine, it can only do its job when you take it as your doctor instructs you. Your doctor prescribed you AUGTYRO to help treat your cancer.

# Remember that some medications, even when working, can cause side effects.

Some side effects may range from feeling uncomfortable to serious.





# Your care team can help you set expectations, and help keep you taking your AUGTYRO as directed.

Because when you know what to expect, you can be more prepared to actively manage your side effects. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with AUGTYRO if you develop side effects.



# Reporting side effects early is important

Talking to your healthcare team about how you are feeling can help them become aware of side effects early. Treating certain side effects early may help keep them from becoming more serious.

# Take an active role in your treatment journey.

Office visits are opportunities to ask your doctor questions.

That's why you have a **Side Effect Tracker** starting on page 11 of this tracker. That's where you can take notes on changes in symptoms or side effects, and keep track of any questions or concerns about your treatment with AUGTYRO.





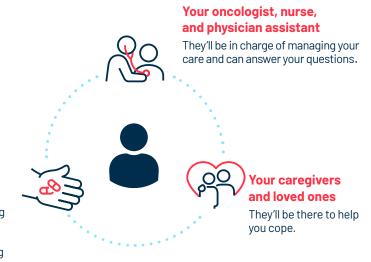
# Always talk to your care team about how to help manage side effects.

Make sure you keep in touch, and follow the advice of your oncologist, nurse and physician assistant, and pharmacist.



# Each part of your care team plays a big role in helping you

## Get to know your care team.



#### Your pharmacist

They are important in not only supplying your medications but also in helping manage your dosing and any side effects.



But you play an important role by letting them all know how you feel

# Your care team is just a call or email away

When you see your care team, ask for their contact information and write it down here.

You'll be able to reach them in case you have any concerns or questions, including about potential side effects.

Oncologist:	Pharmacist:
Phone number:	Phone number:
Email address:	Email address:
Nurse:	Cararivary
	Caregiver:
Phone number:	
Email address:	Email address:
Primary care physician:	Other important contact:
Phone number:	
Email address:	
Physician assistant:	
Phone number:	_
Email address:	



## Your daily side effects check-in

You have a lot on your mind, so it may be difficult to remember any changes in how you're feeling over time. Use this Daily Side Effects Check-in to help you:

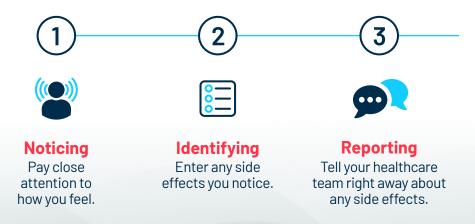
- Keep track of how you're doing on treatment
- Communicate the details of how you're feeling to your healthcare team

#### It includes:

- Pages to record any side effects you notice
- A list of potential side effects to refer to on page 9

Remember to bring your check-in tracker with you to every doctor appointment.

# Use them together to start a daily **3-step routine** of



## Common side effects you can track

Remember, contact your care team as soon as you have any side effect concerns. See page 7 for a place where you can write down contact information.

- Dizziness
- Change in sense of taste
- Feeling of numbness or tingling in your arms or legs
- Constipation
- Shortness of breath
- Tiredness

- Trouble with balance, coordination, and walking
- Problems with thinking, such as forgetfulness or confusion, memory problems, and hallucinations
- Muscle weakness
- Nausea



#### These are not all the possible side effects.

Talk to your doctor for more information about side effects. If you think you feel any of these symptoms, or any others that concern you, get in touch with your care team right away.

#### If you're experiencing dizziness, here are some tips that may help:



Drink plenty of fluids. Aim for 8 to 12 eight-ounce glasses of water or other fluids each day



Walk slowly and carefully if you are dizzy. Hold handrails when using stairs



Avoid drinking a lot of coffee, tea, soda, and other beverages with caffeine



Consider using a walking stick or cane to help you keep your balance



Change positions slowly. For example, sit up carefully from a lying position. If you get dizzy when you stand up, hold a chair or table for balance and stand up more slowly than usual



Avoid driving if you are often dizzy. Do not drive or operate machinery until your symptoms have resolved

The tips provided here are for informational purposes only and are not meant to replace a physician's medical advice. Please contact your healthcare team if you are experiencing dizziness and ask your doctor if these tips may be right for you.



# How to use your Daily Check-in

- 1 Be aware of what to look out for
  - Use the list of potential side effects on page 9 to help you identify and describe how you're feeling.
- 2 For your first 2 weeks taking AUGTYRO, make a habit of keeping track every day.

Make an entry in your Daily Check-In chart at the same time every day. Here's an example:

Date	Any side effects?	How severe?	Name and describe side effects
11/18	<b>⊗</b> N	1 7 3	Diarrhea
Indicate w not you've any side ef day by ch "Yes" on	e noticed fects that necking	Score the si effect severity 1=mild 2=moderat 3=severe	y as: column to name your side effects.

From Week 3 on, write in your tracker only when you feel side effects.

Over time, you and your doctor will be able to see if side effects increase, decrease, or stay the same. All side effects, even those that may seem mild, should be discussed with your healthcare team right away.

This may help keep your side effects from becoming more serious. For additional charts, please call AUGTYRO with You at 1-877-AUGTYRO (1-877-284-8976).

# Your Daily Check-in: Weeks 1 and 2

#### Week 1

Date	Any side effects?	How severe?	Name and describe side effects
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	
	Y N	1 2 3	
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	

#### Week 2

Date	Any side effects?	How severe?	Name and describe side effects
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	
	(Y) (N)	1 2 3	



# Week 3 onward

Date	How severe?	Name and describe side effects
	1 2 3	
	1 2 3	
	1 2 3	
	1 2 3	
	1 2 3	
	1 2 3	
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Date	How severe?	Name and describe side effects
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Date	How severe?	Name and describe side effects
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Date	How severe?	Name and describe side effects
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# **Help You Stay You**

During this journey, remember that you're not alone. Reach out to your healthcare team, caregivers, friends, and loved ones. Here are some organizations that offer support to help you stay you.\*

- ROS1ders theros1ders.org
- LUNGevity
   <u>lungevity.org</u>
- G02 for Lung Cancer go2.org
- Lung Cancer Foundation of America <u>lcfamerica.org</u>
- Lung Cancer Research Foundation lungcancerresearchfoundation.org
- American Lung Association lung.org
- A Breath of Hope Lung Foundation youandlungcancer.com

\*Bristol Myers Squibb does not endorse these organizations. The information/ links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician's medical advice.

## Sign up for the



# We can help you feel more supported throughout your treatment journey.

This free program includes helpful information, details about support and advocacy groups, and useful tips and resources to stay encouraged.

Sign up here





## **Important Facts** about AUGTYRO® (repotrectinib)

This is a summary of important information that you need to know about AUGTYRO. Your healthcare team can work with you to help answer any questions you may have about this medication. Keep this document in a safe place, so you can refer to it before and during your treatment.

Look out for the following icons as you read:





**f** Helpful information to remember

#### What is AUGTYRO?

AUGTYRO (repotrectinib) is an oral 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 with ROS1-positive NSCLC.



Talk to your healthcare team for more information about what it means to have an abnormal ROS1 gene.

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

AUGTYRO may cause serious side effects. A serious side effect is a side effect that can sometimes become life-threatening and can lead to death. The serious side effects of AUGTYRO may include:

**Central nervous system (CNS) problems.** Symptoms to look out for include:

- dizziness
- vertigo
- such as anxiety, irritability, and depression
- balance or coordination seeing or hearing problems
- changes in mood,
   problems with thinking, such as forgetfulness or confusion
- things that are not real (hallucinations)
- problems with concentration, attention, memory, and sleep

• Call your healthcare provider right away if you have any of these symptoms, or any worsening of CNS effects during treatment.

Lung problems (pneumonitis). AUGTYRO may cause pneumonitis (inflammation of the lungs), which may be severe or serious. New or worsening symptoms to look out for include:

- Dry cough Productive cough Wheezing
   Trouble breathing (without (with mucus) mucus)
- **Call your healthcare provider right away** if you have any of these symptoms, or any worsening of your current lung problems.

Liver problems. Your healthcare provider will do blood tests to check your liver function before starting treatment with AUGTYRO, every 2 weeks for the first month, and as needed during treatment. Symptoms of liver problems include:

- vour skin or the white part of your eyes turns yellow
- dark or "teacolored" urine
- light-colored stools (bowel movements)
- loss of appetite
- nausea or vomiting
- pain on the upper right side of your stomach area
- Call your healthcare provider right away if you develop any of these symptoms of liver problems.

Muscle problems. Your healthcare provider will do blood tests before starting treatment with AUGTYRO, every 2 weeks for the first month, and as needed during treatment. Symptoms of muscle problems include:

- unexplained muscle pain
   tenderness or muscle pain that does not go away
- weakness





Increased uric acid level in your blood (hyperuricemia). AUGTYR0® 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
   nausea or of urine or no urine at all
- vomitina
  - 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.

**Call your healthcare provider right away** if you have pain, changes in movement, or bone abnormalities.

#### What should I discuss with my healthcare team before starting treatment?



Talk to 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 or kidney problems



Talk to your healthcare team about all the medicines you are taking, including:

- prescription medicines
- over-the-counter
   vitamins
   herbal medicines

supplements

Taking AUGTYRO with certain other medicines may:

- affect the amount of AUGTYRO or other medicines in your blood,
- cause side effects, and/or
- affect the way that AUGTYRO or other medicines work.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

These are not all the topics you should discuss with your healthcare team. Discuss any questions you may have with your healthcare team.

#### What should I discuss with my healthcare team about pregnancy, birth control, and breastfeeding before starting treatment?



Talk to your healthcare team if:



#### You are pregnant or plan to become pregnant -AUGTYR0® may harm your unborn baby

If you are able to become pregnant, your healthcare team should do a pregnancy test before you start treatment with AUGTYRO.

If you are able to become pregnant, you should use effective non-hormonal birth control (contraception) during treatment and for 2 months after your 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 team about birth control methods that may be right for you.



Call your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with AUGTYRO.

#### You are a male with a female partner who is able to become pregnant

You should use effective birth control during treatment with AUGTYRO and for 4 months after your last dose.



Call your healthcare provider right away if your partner becomes pregnant during treatment with AUGTYRO.



#### You are breastfeeding or plan to breastfeed

Do not breastfeed during treatment and for 10 days after the last dose of AUGTYRO. It is not known if AUGTYRO passes into your breast milk. Talk to your healthcare team about the best way to feed your baby during this time.



#### What are the most common side effects of AUGTYR0°?

The most common side effects of AUGTYRO include:

- Dizziness
- Change in sense of taste
- Feeling of numbness or tingling in your arms or legs

Constipation

- Shortness of breath
- Tiredness
- Trouble with balance, coordination, and walking
- Problems with thinking, such as forgetfulness or confusion, memory problems, and hallucinations
- Muscle weakness
- Nausea

These are not all the possible side effects. **Talk to your doctor** for more information about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA by visiting <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a> or calling 1-800-FDA-1088.

#### How should AUGTYRO be taken?

Take AUGTYRO exactly as your healthcare provider tells you.

The number of pills that you take will depend on your dose. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with AUGTYRO if you develop side effects. Do not change your dose or stop taking AUGTYRO without first talking to your healthcare provider.



AUGTYRO is a capsule with a white opaque cap and body, filled with a white to off-white powder. "REP 40" is printed in blue text on the cap.

**Inactive ingredients:** microcrystalline cellulose, sodium lauryl sulfate, croscarmellose sodium, and colloidal silicon dioxide.

**Capsule coating inactive ingredients:** gelatin and titanium dioxide.

**Printing ink:** shellac and FD & C blue #2 aluminum lake.

#### OR



AUGTYRO is a capsule with a blue opaque cap and body, filled with a white to off-white powder. "REP 160" is printed in white text on the cap.

**Inactive ingredients:** microcrystalline cellulose, sodium lauryl sulfate, croscarmellose sodium, magnesium stearate, and colloidal silicon dioxide.

**Capsule coating inactive ingredients:** gelatin and titanium dioxide.

**Printing ink:** shellac, titanium dioxide, and FD & C blue #1.

- Do take AUGTYRO with or without food
- ✓ **Do** take AUGTYRO at about the same time each day, such as in the morning or in the evening\*
- ✓ Do swallow AUGTYRO capsules whole with water
  - \*Setting an alarm clock or a calendar notification is a great way to remember to take medication.

- Do not open, crush, chew, or dissolve the capsule.
  Do not take broken, cracked, or damaged capsules
- ➤ **Do not** eat grapefruit or drink grapefruit juice during treatment with AUGTYRO
- ➤ **Do not** drive or operate machinery until you know how AUGTYRO affects you and you no longer have symptoms



#### What if I miss a dose of AUGTYRO®?

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.

#### How do I store AUGTYRO?

AUGTYRO capsules should be stored at room temperature between  $68^{\circ}$ F to  $77^{\circ}$ F ( $20^{\circ}$ C to  $25^{\circ}$ C).

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



For more information, please see U.S. Full <u>Prescribing</u> <u>Information</u> and Patient Information for AUGTYRO. Talk to your healthcare team for more information about this medication.

# Any other notes?

reatment with AUGTYRO that you'd like to discuss with your doctor.			or.	

Use this space to write down anything else you'd like to note about your



# Keep track of your treatment with



If you have any questions about your side effects, talk to your doctor or care team.

Please see additional Important Safety Information throughout and U.S. Full <u>Prescribing Information</u> for AUGTYRO.



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