

# AUGTYRO®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I using AUGTYRO?

AUGTYRO contains the active ingredient repotrectinib. AUGTYRO is used to treat adults with a type of lung cancer called 'non-small cell lung cancer' (NSCLC) that is caused by a change in the ROS1 gene. For more information, see Section [1. Why am I using AUGTYRO?](#) in the full CMI.

## 2. What should I know before I use AUGTYRO?

**Do not use if you have ever had an allergic reaction to AUGTYRO or any of the ingredients listed at the end of the CMI.**

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use AUGTYRO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with AUGTYRO and affect how it works. It is important to check the list of medicines in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use AUGTYRO?

Your doctor will tell you how much AUGTYRO to take. Take AUGTYRO by mouth – with or without food. Swallow each capsule whole. Do not open, crush, chew or dissolve the contents of the capsules. More instructions can be found in Section [4. How do I use AUGTYRO?](#) in the full CMI.

### 5. What should I know while using AUGTYRO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor (including surgeon), dentist or pharmacist you visit that you are using AUGTYRO.</li></ul>
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- Tell your doctor straight away if you get any of these symptoms during treatment:
  - muscle pain, tenderness or weakness;
  - bone pain or fractures;
  - yellowing of your eyes or skin, tea-coloured urine, nausea, vomiting associated with liver problems;
  - red, hot, tender, or swollen joints, a decrease in urine production, blood in your urine, pain in your stomach area or sides, nausea or vomiting. These are symptoms of increased uric acid;
  - dizziness, confusion, changes in mood, hallucinations or memory problems, or lose muscle coordination, walk uncoordinatedly or unsteadily;

	<ul style="list-style-type: none"> <li>◦ shortness of breath, cough, or fever.</li> <li>• Tell your doctor immediately if you become pregnant while taking this medicine.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking AUGTYRO unless your doctor tells you to.</li> <li>• Do not take AUGTYRO if you are pregnant or planning to become pregnant.</li> <li>• Do not drink grapefruit juice or eat grapefruit while on treatment with AUGTYRO</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• If you feel dizzy while taking this medicine, do not drive a vehicle, cycle or use any tools or machines.</li> </ul>

For more information, see Section [5. What should I know while using AUGTYRO?](#) in the full CMI.

## 6. Are there any side effects?

Like all medicines, AUGTYRO can cause side effects. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment.

Some side effects can be serious and you may require medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## AUGTYRO<sup>®</sup> (aug-TYE-ro)

**Active ingredient(s):** *Repotrectinib*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using AUGTYRO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AUGTYRO.**

**Where to find information in this leaflet:**

- [1. Why am I using AUGTYRO?](#)
- [2. What should I know before I use AUGTYRO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use AUGTYRO?](#)
- [5. What should I know while using AUGTYRO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using AUGTYRO?**

**AUGTYRO contains the active ingredient repotrectinib.**

**AUGTYRO is used to treat is used to treat adults with a type of lung cancer called ‘non-small cell lung cancer’ (NSCLC) that is caused by a change in the ROS1 gene.**

AUGTYRO is used when:

- a test has shown that your cancer cells have a change in a gene called ‘ROS1’, and
- your cancer is advanced – for example, has spread to other parts of your body (metastatic).

The ROS1 gene contains instructions for making ROS1 proteins. AUGTYRO works by blocking the action of proteins that do not work properly as a result of a Changes in the ROS1 gene resulting in abnormal ROS1 proteins can cause cancer cells to grow uncontrollably. By blocking the abnormal ROS1 proteins, AUGTYRO may slow or stop cancer cell growth and may help shrink your cancer.

## **2. What should I know before I use AUGTYRO?**

### **Warnings**

**Do not use AUGTYRO if:**

- you are allergic to repotrectinib, or any of the ingredients listed at the end of this leaflet.
- you are pregnant or plan to become pregnant

Always check the ingredients to make sure you can use this medicine.

### **Do not take AUGTYRO with the following:**

- Do not drink grapefruit juice or eat grapefruit during your treatment with AUGTYRO. It may increase the amount of the medicine in your blood to a harmful level.

### **Check with your doctor if you have any other medical conditions.**

Talk to your doctor, pharmacist or nurse before taking AUGTYRO if:

- you have recently experienced dizziness, memory loss, confusion, hallucinations, mental status changes, loss of muscle coordination, or uncoordinated or unsteady walking.
- you have ever had any other lung problems. Tell your doctor right away if you have any new or worsening symptoms including shortness of breath, or cough, or fever.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)



## **Pregnancy and breastfeeding**

### **Pregnancy**

You/ your partner should avoid becoming pregnant while taking this medicine because it could harm the baby.

### **Tell your doctor straight away:**

- if you become pregnant while you are taking this medicine, or during the 2 months after taking your last dose, tell your doctor straight away.
- if you get your partner pregnant while you are taking this medicine, or during the 4 months after taking your last dose.

### **Contraception (birth control)**

Talk to your doctor about the right methods of contraception for you and your partner.

If you are able to become pregnant, use a highly effective method of contraception while on treatment and for at least 2 months after stopping treatment.

If your partner is able to become pregnant, use a highly effective method of contraception while on treatment and for at least 4 months after stopping treatment.

Methods that rely on hormones (like oral contraceptive pills, injections, or patches applied to the skin) may not work during treatment with AUGTYRO, so use effective non-hormonal contraception (like condoms)

### **Breast-feeding**

Do not breast-feed while taking this medicine. This is because it is not known if AUGTYRO can pass over into breast milk and could therefore harm your baby.

### **3. What if I am taking other medicines?**

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including prescription, non-prescription or herbal medicines.**

This is because certain medicines (or foods, like grapefruit) can affect the levels of AUGTYRO in your body.

AUGTYRO can affect the levels of certain medicines, too. This can change how well AUGTYRO or the other medicine works.

**Tell your doctor if you are taking, have recently taken or might take:**

- medicines to treat Acquired Immune Deficiency Syndrome (AIDS)/Human immunodeficiency virus (HIV) infection – such as ritonavir or saquinavir
- medicines to treat fungal infections (anti-fungals) – such as ketoconazole, itraconazole, voriconazole, posaconazole
- medicines to stop seizures or fits (anti-epileptics) – such as carbamazepine or phenytoin
- medicines for tuberculosis – such as rifampin
- a herbal medicine for depression – St. John's Wort

- medicines to treat solid cancers and blood cancer – apalutamide
- medicines to suppress your body's immune system, or prevent the body from rejecting an organ transplant – sirolimus, tacrolimus, cyclosporin
- a medicine used for strong pain relief called alfentanil
- medicines for depression – bupropion

If you are not sure whether you are taking any of the medicines mentioned above, ask your doctor or pharmacist.

Before stopping or changing the dose of a medicine or starting a new medicine, tell your doctor or pharmacist.

## **4. How do I use AUGTYRO?**

### **How much to take / use**

The recommended dose is 160 mg once a day for the first 14 days, followed by 160 mg twice a day until your doctor tells you otherwise.

Depending on how you respond to the treatment, your doctor may suggest a lower dose, or even pausing treatment. For lower doses, you may need to take multiple capsules (because they only come in 40mg or 160mg strengths).

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

**Always take AUGTYRO as prescribed by your doctor.**

## **Taking this medicine**

- Take AUGTYRO by mouth – with or without food.
- Swallow each capsule whole.
- Do not open, crush, chew or dissolve the contents of the capsules.

## **If you forget to use AUGTYRO**

If you missed a dose or vomited after taking a dose, take the next dose as prescribed. Do not take a double dose to make up for a missed dose.

## **If you stop taking AUGTYRO**

Do not stop taking this medicine without talking to your doctor first. It is important to take AUGTYRO every day for as long as your doctor prescribes it for you. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **If you use too much AUGTYRO**

If you think that you have used too much AUGTYRO, you may need urgent medical attention. Talk to a doctor or go to hospital straight away. Take the medicine pack and this leaflet with you.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using AUGTYRO?**

### **Things you should do**

- Keep all of your doctor's appointments so that your progress can be checked.
- Tell any other doctors (including surgeons), dentists and pharmacists who are treating you that you are being treated with AUGTYRO.
- Tell your doctor immediately if you become pregnant or plan to become pregnant while being treated with AUGTYRO.

### **Things you should not do**

- Do not stop using this medicine unless your doctor tells you to.
- Do not stop or change the dose of a medicine or start a new medicine without telling your doctor.
- Do not drink grapefruit juice or eat grapefruit while on treatment with AUGTYRO.

**Call your doctor straight away if you get any of these symptoms during your treatment with AUGTYRO:**

- you feel dizzy, confused, have changes in mood, hallucinations (see things that are not there) or memory problems (cognitive disorders), or lose muscle coordination, walk uncoordinatedly or unsteadily (ataxia).
- you have shortness of breath (dyspnoea), cough, or fever (pyrexia).
- you develop symptoms of liver problems including: your skin or the white part of your eyes turns yellow, loss of appetite, dark or "tea-coloured" urine, light coloured stools (bowel movements), nausea or vomiting, or pain on the upper right side of your stomach.
- muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.
- 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, or pink or brown urine or blood in your urine.
- bone fractures (with or without a fall or other injury), pain, changes in movement, or bone abnormalities.

Your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely:

Remind any doctor (including surgeon), dentist or pharmacist you visit that you are using AUGTYRO.

## **Driving or using machines**

**AUGTYRO may affect your ability to drive or use machines. AUGTYRO may cause you to:**

- feel dizzy
- impaired balance or coordination
- pass out (lose consciousness)
- feel tired
- have changes in your mental status, feel confused or see things that are not there (hallucinations)
- have blurred vision

If this happens, you should not drive, use a bicycle, or operate heavy machinery until your symptoms resolve. Talk to your doctor or pharmacist about whether it is okay for you to drive, cycle or use machines.

## **Looking after your medicine**

**Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date which is stated on the bottle, blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. It is recommended to store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and ask your doctor or pharmacist if you have any further questions about side effects.

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• central nervous system effects such as dizziness, vertigo, changes in mood, anxiety, irritability, depression, balance and</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>



Serious side effects	What to do
<p>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, loss of muscle coordination, walking uncoordinatedly or unsteadily (ataxia).</p> <ul style="list-style-type: none"> <li>● Lung problems (pneumonitis): new or worsening symptoms of lung problems, including dry cough (without mucus), productive cough (with mucus), wheezing or trouble breathing, shortness of breath (dyspnoea) or fever (pyrexia).</li> <li>● Liver problems symptoms that include: your skin or the white part of your eyes turning yellow, dark or "tea-coloured urine", light-coloured stools (bowel movements), loss of</li> </ul>	<p><b>notice any of these side effects.</b></p>

Serious side effects	What to do
<p>appetite, nausea or vomiting, pain on the upper right side of your stomach area.</p> <ul style="list-style-type: none"> <li>● Muscle problems: new or worsening signs and symptoms, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.</li> <li>● Increased uric acid level in your blood (hyperuricemia): 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.</li> <li>● Bone fractures: pain, changes in movement, or bone abnormalities</li> </ul>	

## Other side effects

Other side effects	What to do
<p><b>Very Common side effects</b></p> <ul style="list-style-type: none"> <li>• taste change (dysgeusia)</li> <li>• sensations like numbness and tingling (paraesthesia) or numbness, tingling, burning (peripheral sensory neuropathy)</li> <li>• constipation</li> <li>• feeling tired (fatigue)</li> <li>• major change in thinking patterns (cognitive disorders)</li> <li>• urge to vomit (nausea)</li> <li>• muscular weakness</li> <li>• headache</li> <li>• sleep disorders</li> <li>• increased blood level of enzyme from muscle (creatine phosphokinase)</li> <li>• weight gain</li> <li>• joint pain (arthralgia)</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

Other side effects	What to do
<ul style="list-style-type: none"> <li>• vomiting</li> <li>• vision disorder</li> <li>• loose or frequent stools (diarrhoea)</li> <li>• muscle pain (myalgia)</li> <li>• leg and/or arm pain</li> </ul> <p><b>Common side effects</b></p> <ul style="list-style-type: none"> <li>• falls</li> <li>• bone fractures</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What AUGTYRO contains

<b>Active ingredient (main ingredient)</b>	Repotrectinib
<b>Other ingredients (inactive ingredients)</b>	<p>Capsule content:</p> <ul style="list-style-type: none"><li>• Microcrystalline cellulose, sodium lauryl sulfate,</li><li>• Croscarmellose sodium,</li><li>• Colloidal silicon dioxide</li><li>• Magnesium stearate (160 mg hard capsules only).</li></ul> <p>Capsule shell:</p> <ul style="list-style-type: none"><li>• Gelatin,</li><li>• Titanium dioxide,</li><li>• Brilliant blue (160 mg hard capsules only).</li></ul> <p>Printing Ink:</p> <ul style="list-style-type: none"><li>• Printing ink (40 mg hard capsules): Shellac</li></ul>

	and indigo carmine aluminum lake • Printing ink (160 mg hard capsules): Shellac and titanium dioxide.
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What AUGTYRO looks like**

AUGTYRO 40 mg hard capsules (capsules) are opaque white with 'REP 40' imprinted in blue. (AUST R 445679)

AUGTYRO 160 mg hard capsules (capsules) are opaque blue with 'REP 160' imprinted in white. (AUST R 445678)

AUGTYRO 40 mg is provided in bottles containing either 60 or 120 hard capsules.

AUGTYRO 160 mg is provided in blisters containing either 20 or 60 hard capsules.

Not all pack sizes may be marketed.

## **Who distributes AUGTYRO**

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: [MedInfo.Australia@bms.com](mailto:MedInfo.Australia@bms.com)

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