

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.

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

1. Why am I using GAVRETO?

GAVRETO contains the active ingredient pralsetinib. GAVRETO is used to treat patients who have certain types of cancer - known as rearranged during transfection (RET)-fusion positive lung cancer or thyroid cancer.

For more information, see Section [1. Why am I using GAVRETO?](#) in the full CMI.

2. What should I know before I use GAVRETO?

Do not use if you have ever had an allergic reaction to GAVRETO 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. It is important to tell you doctor if you have a history of lung and/or breathing problems, high blood pressure, liver problems or bleeding problems.

For more information, see Section [2. What should I know before I use GAVRETO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GAVRETO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use GAVRETO?

- The recommended dose is 400 mg (4 capsules) taken by mouth once daily. GAVRETO capsules should be swallowed whole with a glass of water and must not be opened or chewed. If you get side effects, your doctor may change your dose, temporarily stop, or permanently stop treatment.
- Take GAVRETO on an empty stomach. Do not eat for at least 2 hours before and at least 1 hour after taking GAVRETO.

More instructions can be found in Section [4. How do I use GAVRETO?](#) in the full CMI.

5. What should I know while using GAVRETO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking GAVRETO.• Your doctor will perform regular checks of your blood pressure, and liver function (via a blood test)• Tell your doctor straight away if you become pregnant• Tell your doctor straight away if you experience any new or worsening symptoms or symptoms that concern you
Driving or using machines	<ul style="list-style-type: none">• GAVRETO may make some people feel fatigued. Be careful driving and/or operating heavy machinery until you know how it affects you
Looking after your medicine	<ul style="list-style-type: none">• Store GAVRETO in a cool, dry place where children cannot access it. GAVRETO should be stored at room temperature (below 30°C).• If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

6. Are there any side effects?

GAVRETO can cause side effects that you need to tell your doctor about straight away. Tell your doctor if you experience any side effects which concern you. Symptoms of serious side effects include difficulty breathing, shortness of breath, fever, yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, vomiting blood, bleeding or bruising more easily than normal. 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.

GAVRETO (GAV-RET-OH)

Active ingredient(s): *pralsetinib* (prowl-set-ee-nib)

GAVRETO has **provisional approval** in Australia for the indications below:

Treatment of adult patients with locally advanced or metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC); and the treatment of adult patients with advanced or metastatic RET-fusion positive thyroid cancer that is refractory to (or unsuitable for) radioactive iodine and who have progressed on or are unable to tolerate lenvatinib or sorafenib.

The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is needed to be submitted when available to fully confirm the benefit and safety of the medicine for these uses.

Consumer Medicine Information (CMI)

This leaflet provides important information about using GAVRETO. **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 GAVRETO.**

Where to find information in this leaflet:

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

1. Why am I using GAVRETO?

GAVRETO contains the active ingredient pralsetinib. GAVRETO is a cancer medicine. In patients whose cancer is due to an altered rearranged during transfection (RET) gene, the change in the gene causes the body to make an abnormal protein called a RET fusion protein, which can lead to uncontrolled cell growth and cancer. GAVRETO blocks the action of RET fusion proteins and may help to slow or stop your cancer from growing. It may also help to shrink your cancer.

GAVRETO is used to treat certain cancers caused by RET genes in:

- **adults with non-small cell lung cancer (NSCLC) that is advanced or spread to other parts of the body (metastatic)**
- **adults with thyroid cancer that is advanced or spread to other parts of the body (metastatic) and who have received radioactive iodine (if suitable); and either lenvatinib or sorafenib (if these are able to be tolerated) and they did not work or are no longer working**

Your healthcare provider will perform a test to make sure that GAVRETO is right for you.

It is not known if GAVRETO is safe and effective in children younger than 18 years of age.

2. What should I know before I use GAVRETO?

Warnings

Do not use GAVRETO if:

- you are allergic to pralsetinib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions i.e. have lung or breathing problems; have high blood pressure; have liver problems or have bleeding problems
- plan to have surgery. You should not use GAVRETO for at least 5 days prior to your surgery
- take any medicines for any other condition

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will perform a pregnancy test before you start treatment with GAVRETO.

Contraception in females:

You should avoid becoming pregnant while taking this medicine. If you are able to have children, you must use highly effective contraception (for example, double-barrier contraception such as condom and diaphragm) while on treatment and for at least 2 weeks after stopping treatment. GAVRETO may reduce the effectiveness of hormonal contraceptive methods (for example, birth control pill); therefore, hormonal contraceptives may not be considered highly effective. If hormonal contraception is unavoidable, it must be used in combination with a condom.

Contraception in males:

Males with female partners of childbearing potential should use effective contraception during treatment and for 1 week after completion of treatment.

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

Pregnancy:

This medicine is not recommended for use during pregnancy unless absolutely necessary. Avoid becoming pregnant while being treated with this medicine as it may harm your unborn baby. Your doctor will discuss with you the potential risks of taking GAVRETO during pregnancy.

Breastfeeding:

It is not known if GAVRETO passes into your breast milk. Do not breastfeed during treatment and for one week after your final dose of GAVRETO.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with GAVRETO and affect how it works.

Medicines that may increase the effect of GAVRETO include:

- Medicines used to treat AIDS/HIV (e.g. ritonavir)
- Medicines used to treat infections. These include medicines that treat fungal infections (antifungals such as ketoconazole, itraconazole, voriconazole, posaconazole) and medicines that treat certain types of bacterial infection (e.g. certain types of antibiotics)

Medicines that may reduce the effect of GAVRETO include:

- Medicines used to stop seizures or fits (anti-epileptics such as phenytoin, carbamazepine or phenobarbital)
- Medicines used to treat tuberculosis (e.g. rifampicin, rifabutin)
- St. John's Wort, a herbal medicine used to treat depression

GAVRETO may affect the way some other medicines work, including:

- ciclosporin
- paclitaxel
- warfarin

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GAVRETO.

4. How do I use GAVRETO?

How much to take

- Follow the instructions provided and use GAVRETO until your doctor tells you to stop. The recommended dose is 400 mg (4 capsules) taken by mouth, once daily.

When to take GAVRETO

- GAVRETO is usually taken once a day.
- Take GAVRETO on an empty stomach. Do not eat for at least 2 hours before and at least 1 hour after taking GAVRETO.
- GAVRETO capsules should be swallowed whole with a glass of water and must not be opened or chewed.
- Do not change your dose or stop taking GAVRETO unless your healthcare provider tells you to. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with GAVRETO.

If you forget to take GAVRETO

GAVRETO should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as possible on the same day. Then take your next dose of GAVRETO at your regular time the next day. If you vomit

after taking a dose of GAVRETO, do not take an extra dose. Take your next dose of GAVRETO at your regular time the next day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much GAVRETO

If you think that you have used too much GAVRETO, you may need urgent medical attention.

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 GAVRETO?

Things you should do

Call your doctor straight away if you:

- if you have any new or worsening symptoms including difficulty in breathing, shortness of breath, or cough with or without mucous, or fever. GAVRETO may cause severe, life-threatening or fatal swelling (inflammation) of the lungs during treatment.
- if you have any yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, feeling less hungry than usual, nausea or vomiting, feeling tired, bleeding or bruising more easily than normal.
- are vomiting blood or vomit that looks like coffee-grounds, coughing up blood or blood clots, have pink or brown urine, red or black (looks like tar) stools, unusual bleeding or bruising of your skin, menstrual bleeding that is heavier than normal, unusual vaginal bleeding, nose bleeds that happen often, drowsiness or difficulty being awakened.

Remind any doctor, dentist or pharmacist you visit that you are using GAVRETO.

While you are taking GAVRETO

- Your doctor will take blood tests before you start treatment, then every 2 weeks for the first 3 months of your treatment and then as needed. This is to check you do not have any liver problems while taking GAVRETO.
- GAVRETO can increase the chance of high blood pressure. Your doctor will monitor your blood pressure before you start treatment, then after 1 week of your treatment and then as needed.
- You should avoid drinking grapefruit juice and eating grapefruit while on treatment with GAVRETO.
- Tell your doctor straight away if you become pregnant or think you might be pregnant during treatment with GAVRETO.
- Wounds may not heal properly during treatment with GAVRETO. You should not take GAVRETO for at least

5 days before surgery. Your doctor should tell you when you may start taking GAVRETO again after surgery.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GAVRETO affects you.

GAVRETO may cause fatigue in some people.

Looking after your medicine

- Store GAVRETO at room temperature (below 30°C).
- Follow the instructions in the carton on how to take care of your medicine properly.
- 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.

Keep it where young children cannot reach it.

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 use this medicine after the expiry date which is stated on the bottle label and outer carton after "EXP". The expiry date refers to the last day of that month.

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, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal system:</p> <ul style="list-style-type: none"> • Constipation • Diarrhoea • Dry Mouth • Nausea • Vomiting <p>General:</p> <ul style="list-style-type: none"> • Tiredness • Muscle and joint pain • Headache • Change in the way things taste <p>Infections:</p> <ul style="list-style-type: none"> • Symptoms of urinary (bladder) infection including strong and frequent urge to urinate. cloudy, bloody, or strong-smelling urine, pain or a burning sensation when urinating <p>Skin:</p> <ul style="list-style-type: none"> • Rash 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Lung problems:</p> <ul style="list-style-type: none"> • Severe or life-threatening inflammation of the lungs. Symptoms include shortness of breath, cough, fever <p>Bleeding problems:</p> <ul style="list-style-type: none"> • Vomiting blood or if your vomit looks like coffee grounds • Pink or brown urine • Red or black (looks like tar) stools • Coughing up blood or blood clots • Unusual bleeding or bruising of your skin • Menstrual bleeding that is heavier than normal • Unusual vaginal bleeding • Nose bleeds that happen often • Drowsiness or difficulty being awakened • Confusion • Headache • Change in speech <p>Liver problems:</p> <ul style="list-style-type: none"> • Yellowing of skin or the white part of your eyes (jaundice) • Dark 'tea-coloured' urine • Sleepiness • Bleeding or bruising • Loss of appetite • Nausea or vomiting • Pain on the upper right side of your stomach • Changes in blood test results i.e. decreased white blood cell, red blood cell and platelet counts; decreased levels of phosphate, calcium or sodium (salt) in the blood • Abnormal liver function blood tests <p>High blood pressure</p> <p>GAVRETO can increase the occurrence of high blood pressure. Symptoms of high blood pressure can include confusion, headaches, shortness of breathe, dizziness and/or chest pain.</p> <p>Abnormal ECG</p> <p>GAVRETO may result in abnormal ECGs. Tell your Doctor if you feel light-headed or experience palpitations as it may be a symptom of abnormal ECG.</p> <p>Tumour Lysis Syndrome (TLS)</p> <p>TLS is caused by fast breakdown of cancer cells, and may lead to serious side effects. Symptoms include:</p> <ul style="list-style-type: none"> • Nausea or vomiting • Weakness 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> Swelling Shortness of breath Seizures Muscle cramps 	

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. 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 GAVRETO contains

Active ingredient (main ingredient)	pralsetinib
Other ingredients (inactive ingredients)	<p>citric acid anhydrous, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch and sodium bicarbonate.</p> <p>Capsule shell: Brilliant Blue FCF, hypromellose and titanium dioxide.</p> <p>White printing ink: TekPrint™ SW-0012 White Ink (PI no. 13175)</p>

Do not take this medicine if you are allergic to any of these ingredients.

What GAVRETO looks like

GAVRETO 100 mg hard capsules are light blue, opaque hard capsules with "BLU-667" printed on the capsule shell body and "100 mg" on the capsule shell cap in white ink (AUST R 380812).

GAVRETO is available in a plastic bottle with child-resistant closure containing 60, 90 or 120 hard capsules and a desiccant sachet. Each carton contains one bottle.

Keep the desiccant sachet in the bottle. The desiccant is a moisture absorbing material filled in a small sachet to protect the capsules from moisture. Do not swallow the desiccant.

Who distributes GAVRETO

GAVRETO is distributed in Australia by:

Roche Products Pty Ltd

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000