

CAPRELSA™

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.

1. Why am I using CAPRELSA?

CAPRELSA contains the active ingredient vandetanib. CAPRELSA is used to treat a type cancer (tumour) in the thyroid gland (found in the throat near the windpipe) called medullary thyroid cancer. It is generally used when the cancer has spread to other parts of the body (metastatic). For more information, see Section [1. Why am I using CAPRELSA?](#) in the full CMI.

2. What should I know before I use CAPRELSA?

Do not use if you have ever had an allergic reaction to vandetanib 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 CAPRELSA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CAPRELSA 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 CAPRELSA?

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. More instructions can be found in Section [4. How do I use CAPRELSA?](#) in the full CMI.

5. What should I know while using CAPRELSA?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using CAPRELSA
- If you are about to be start on any new medicine, remind your doctor and pharmacist that you are taking CAPRELSA.

	<ul style="list-style-type: none">● If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.● CAPRELSA may increase your chance of getting sunburnt. Be sure to avoid exposure to the sun.● Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">● Do not stop using this medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen.● Do not take CAPRELSA if you have a heart disorder that you were born with called 'congenital long QT syndrome'.● Do not give this medicine to a child (under 18 years).● Do not give your medicine to anyone

	else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how CAPRELSA affects you. • This medicine may cause tiredness, weakness and blurred vision in some people. If you have any of these symptoms, do not drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none"> • Store it in a cool dry place where the temperature stays below 30°C. • Keep it where children cannot reach it.

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

6. Are there any side effects?

Serious side effects may include severe diarrhoea; severe skin reactions which may include redness or swelling of your face, hands, or soles of your feet, itching

or blisters. For more serious side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Common side effects may include mild diarrhoea; nausea; vomiting, loss of appetite (anorexia), weight loss, dehydration, skin rash/acne including hand and foot rash, skin sensitivity to sunlight; symptoms of sunburn (redness, itching, swelling or blistering), tiredness; fatigue. For more common side effects, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CAPRELSA™

Active ingredient: *vandetanib*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using CAPRELSA?

CAPRELSA contains the active ingredient vandetanib. CAPRELSA belongs to a group of medicines called antineoplastics.

CAPRELSA is used to treat a type of cancer (tumour) in the thyroid gland (found in the throat near the windpipe) called medullary thyroid cancer. It is

generally used when the cancer has spread to other parts of the body (metastatic).

CAPRELSA works by slowing down the growth of new blood vessels in tumours (cancers). This cuts off the supply of food and oxygen to the tumour. CAPRELSA may also act directly on cancer cells to kill them or slow down their growth.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

2. What should I know before I use CAPRELSA?

Warnings

Do not use CAPRELSA if:

- you are allergic to vandetanib, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives on the skin
- Always check the ingredients to make sure you can use this medicine.
- you have a heart disorder that you were born with called 'congenital long QT syndrome'. This is seen on an ECG (electrocardiogram)

CAPRELSA is not likely to affect your ability to drive or use machines. However, if you feel weak or tired or your vision is blurred whilst taking this medicine, take care when you are driving or using tools or machines.

CAPRELSA may increase your chance of getting sunburnt. You should take special care to protect yourself from the sun.

Do not give this medicine to a child (under 18 years).

Safety and effectiveness in children has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have any other medical conditions:
 - Heart or blood pressure problems

- Kidney problems
- Liver problems
- an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.
- Plan to have any surgery before starting or during treatment. CAPRELSA may affect the healing of any wounds. Your doctor will advise you when to stop taking CAPRELSA before surgery and when you may start taking CAPRELSA again after 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

Check with your doctor if you are pregnant or intend to become pregnant.

CAPRELSA may harm an unborn child. If you are pregnant, you should not take CAPRELSA. Women at risk of becoming pregnant must use effective contraception when they are taking CAPRELSA and for at least four months after the last dose of CAPRELSA. Your doctor can discuss with you the risks and benefits involved.

If you are a fertile man, you must use effective contraception during treatment with CAPRELSA and for at least four months after your last dose of CAPRELSA.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

For the safety of your baby, you should discontinue breast-feeding during treatment with CAPRELSA. Your doctor can discuss with you the risks and benefits involved.

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 CAPRELSA and affect how it works, and some medicines may be affected by CAPRELSA. These medicines include:

- medicines used to treat infections such as itraconazole, ketoconazole, ritonavir, clarithromycin and rifampicin
- medicines used to control seizures such as carbamazepine and phenobarbital
- ondansetron - a medicine used to treat nausea and vomiting
- medicines used to treat mental illness such as haloperidol and chlorpromazine
- vitamin K antagonists and dabigatran often referred to as 'blood thinners'
- cyclosporin and tacrolimus - medicines used to treat transplant rejection

- digoxin - a medicine used to treat heart problems
- metformin - a medicine used to control your blood sugar
- medicines used to treat heartburn such as cisapride and proton pump inhibitors

You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How do I use CAPRELSA?

How much to take

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.
- The usual dose is 300 mg once a day (as three 100 mg tablets).
- If you have kidney problems, your doctor may start you on a lower dose (200 mg once a day).
- Your doctor may also reduce your dose down to 200 mg or 100 mg a day if you have certain side effects. .
- Follow the instructions provided and use CAPRELSA until your doctor tells you to stop.

How to take CAPRELSA

- Swallow the tablets whole. If you have trouble swallowing the tablet, you can mix it with water as follows:
- Take half a glass (50 mL) of still (non-carbonated) water only. Do not use any other liquid.
- Put the tablet into the water.
- Stir the tablet until it has dispersed into the water. This may take about 10 minutes.
- Then drink it straight away.
- To make sure there is no medicine left, rinse the empty glass very well with another half a glass of water and drink it.

When to take CAPRELSA

- CAPRELSA should be used at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter if you take this medicine before or after food.

How long to take it

- Continue taking your medicine for as long as your doctor tells you.

If you forget to use CAPRELSA

If it is less than 12 hours before 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 CAPRELSA

If you think that you have used too much CAPRELSA, you may need urgent medical attention. Symptoms of an overdose may include an increase in frequency or severity of some of the side effects listed below such as rash, diarrhoea, high blood pressure (you may have headaches, dizziness, nose bleeds etc.) and effects to your heart (including racing heart, and possible loss of consciousness).

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 CAPRELSA?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CAPRELSA.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Call your doctor straight away if you:

- become pregnant while taking this medicine.
 - Women at risk of becoming pregnant must use effective contraception when they are taking CAPRELSA and for at least four months after the last dose of CAPRELSA.

Be sure to avoid exposure to the sun. Always protect yourself when you go outside by using sun block and wearing sun-protective clothing which covers as much skin as possible. Some people who are taking CAPRELSA become more sensitive to the sun. This can cause sunburn.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests (e.g. ECG heart test, blood tests, urine tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

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

Things you should not do

- Do not stop using this medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen.
- Do not take CAPRELSA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

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

This medicine may cause tiredness, feeling weak and blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- If you take the tablets out of the pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C 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.

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 data-bbox="204 432 724 533">Gastrointestinal or gut related:</p> <ul data-bbox="204 568 783 913" style="list-style-type: none"><li data-bbox="204 568 783 846">● Mild or moderate diarrhoea; nausea; vomiting; loss of appetite (anorexia); weight loss; dehydration<li data-bbox="204 869 580 913">● Abdominal pain <p data-bbox="204 943 491 987">Skin related:</p> <ul data-bbox="204 1025 772 1906" style="list-style-type: none"><li data-bbox="204 1025 772 1126">● Skin rash/acne including hand and foot rash<li data-bbox="204 1149 772 1417">● Dry or itching skin, small raised acne-like bumps usually on the face, scalp, chest and upper back<li data-bbox="204 1440 772 1832">● Skin sensitivity to sunlight; symptoms of sunburn (redness, itching, swelling or blistering) that may occur more quickly than normal<li data-bbox="204 1854 762 1906">● Impaired wound healing <p data-bbox="204 1928 555 1973">Muscle related:</p>	<p data-bbox="817 432 1378 651">Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Muscle weakness/loss of energy <p>Head related:</p> <ul style="list-style-type: none"> ● Headache; nose bleeds ● Blurred vision including halos; dry eye; irritation of the inner eyelid or surface of the eye; other issues with your eye sight <p>Bleeding related:</p> <ul style="list-style-type: none"> ● Blood in the urine <p>Other:</p> <ul style="list-style-type: none"> ● Tiredness; fatigue; trouble sleeping ● Dry mouth; irritation or ulcers of the lining of the mouth, lips or tongue; changes in taste of food ● Unusual hair loss or thinning; nail problems ● Depression 	

Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 724 533">Gastrointestinal or gut related:</p> <ul data-bbox="204 568 619 618" style="list-style-type: none"><li data-bbox="204 568 619 618">• Severe diarrhoea <p data-bbox="204 645 491 689">Skin related:</p> <ul data-bbox="204 725 762 1402" style="list-style-type: none"><li data-bbox="204 725 762 1402">• Severe skin reactions affecting large areas of your body and may include redness or swelling of your face, hands, or soles of your feet, itching, blisters and bleeding of the lips, nose, eyes, mouth or genitals, peeling of your skin, muscle or joint aches <p data-bbox="204 1429 769 1473">Allergic reaction related:</p> <ul data-bbox="204 1509 762 1805" style="list-style-type: none"><li data-bbox="204 1509 762 1626">• Breathlessness/chest tightness<li data-bbox="204 1639 762 1805">• Shortness of breath and swelling of the feet or ankles <p data-bbox="204 1832 692 1926">Heart or blood vessel related:</p>	<p data-bbox="817 432 1378 819">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"> ● Changes in heart rhythm, fainting or dizziness ● Stroke which may include symptoms such as loss of vision in one eye, double vision, dizziness/spinning sensation; weakness in one side of the body, or in the arms or legs; slurred speech and/or loss of co-ordination ● Symptoms of enlargement and weakening of a blood vessel wall (aneurysm) or a tear in a blood vessel wall (arterial dissections) which may include a sudden and extremely severe headache, neck pain, blurry or double vision, sensitivity to light, drooping eyelid, eye pain, pulsing sound in the ear <p>Other:</p> <ul style="list-style-type: none"> ● Cough 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● Fever ● Sudden onset of cramping pain in lower back and/or side, groin or abdomen ● Seizures, headache, confusion/difficulty concentrating ● Renal (Kidney) failure 	

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.

Some side effects for example, thyroid function, liver function, and changes in your blood, urine or heart rhythm may only be found when your doctor does tests from time to time to check your progress.

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 CAPRELSA contains

Active ingredient (main ingredient)	vandetanib (100 mg)
Other ingredients (inactive ingredients)	Calcium hydrogen phosphate dihydrate (E341) Microcrystalline cellulose (E460) Crospovidone Povidone Magnesium stearate Hypromellose (E464) Macrogol 300 Titanium dioxide (E171)
Potential allergens	None.

	This medicine does not contain lactose, sucrose, tartrazine or any other azo dyes.
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Do not take this medicine if you are allergic to any of these ingredients.

What CAPRELSA looks like

CAPRELSA 100 mg is a white biconvex-shaped tablet with "Z100" imprinted on one side and plain on the other (AUST R 192496).

CAPRELSA comes in a blister pack of 30 tablets.

Who distributes CAPRELSA

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park

NSW 2113

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