

VERZENIO™

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 VERZENIO?

VERZENIO contains the active ingredient abemaciclib. VERZENIO is used to treat patients with certain types of breast cancer which have not spread to other parts of the body or spread beyond the original tumour and/or to other organs.

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

2. What should I know before I use VERZENIO?

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

3. What if I am taking other medicines?

Some medicines may interfere with VERZENIO 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 VERZENIO?

- Swallow tablet whole with a full glass of water
- Do not chew, crush or split the tablets before swallowing. VERZENIO may be taken with or without food.

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

5. What should I know while using VERZENIO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or anaesthetist you
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	<p>visit that you are using VERZENIO.</p> <ul style="list-style-type: none"> • If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine or lower the dosage without checking with the doctor. • Do not take grapefruit products while on this therapy as it may increase the side effects.
Driving or using machines	<ul style="list-style-type: none"> • This medicine may cause fatigue and dizziness in some people. • If you have any of these symptoms, do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none"> • Be careful when drinking alcohol while you are taking this medicine. • This medicine may cause fatigue and dizziness in some people.

Looking after your medicine	<ul style="list-style-type: none"> • Keep your tablets in a cool dry place where the temperature stays below 30°C. • Keep your tablets in the pack until it's time to take them.
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For more information, see Section [5. What should I know while using VERZENIO?](#) in the full CMI.

6. Are there any side effects?

Very common: diarrhoea, abdominal pain, infections, nausea, feeling tired, vomiting, constipation, indigestion or upset stomach, decreased appetite, abnormalities in liver blood tests, hair loss, alteration in taste, headache, dizziness, swelling in upper and lower limbs (peripheral oedema), cough, shortness of breath, dry mouth, inflammation of the mouth and lips (stomatitis) rash, itching, dry skin, nail disorders such as breaking or splitting of nails, watering eyes, muscular weakness, flu-like symptoms, fever, decreased weight.

Serious side effects: fever or chills, blood clots in the veins or cough, difficulty breathing or chest discomfort (lung inflammation).

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.

VERZENIO™

Active ingredient: *Abemaciclib*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using VERZENIO?

VERZENIO contains the active ingredient abemaciclib. VERZENIO belongs to a group of medicine called antineoplastic drugs, an anticancer drug.

VERZENIO is used to treat patients with certain types of breast cancer (hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) which have not spread to other parts of the body (early breast cancer) or spread beyond the original tumour and/or to other organs (metastatic breast cancer).

2. What should I know before I use VERZENIO?

Warnings

Do not use VERZENIO if:

- you are allergic to abemaciclib, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- you have an intolerance to some sugars. VERZENIO contains lactose (a type of sugar found in milk and dairy products).

Check with your doctor if you:

- have any other medical conditions. Severe liver problems; blood clots in the veins or arteries, infections, inflammation and infection of the lung
- take any medicines for any other condition.
- pregnant or breast feeding.
- a family history of blood clots.

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

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.

You should use effective birth control (contraception) during treatment with VERZENIO and for 3 weeks after the last dose of VERZENIO.

Do not breast-feed if you are taking this medicine and for at least 3 weeks after the last dose of VERZENIO.

It is not known if VERZENIO is excreted into breast milk and if the breast-fed infant is at risk of harm. Talk to your doctor about breast-feeding during or after treatment with VERZENIO.

VERZENIO may decrease fertility in men.

Child or adolescent

- **Do not give this medicine to a child or adolescent under the age of 18 years.** Safety and effectiveness in children younger than 18 years have not been established.

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 VERZENIO and affect how it works, or VERZENIO may affect how other medicines work.

These can either increase or decrease the amount of abemaciclib in the blood.

Medicines that may increase the effect of VERZENIO include:

- Clarithromycin (antibiotic used to treat bacterial infections).
- Ketoconazole, itraconazole, voriconazole, posaconazole (used to treat fungal infections).
- Diltiazem (used to treat chest pain (angina) and high blood pressure).
- Verapamil (used to treat chest pain (angina), high blood pressure and heart rhythm problems).

- Lopinavir/ritonavir (used to treat HIV/AIDS).

Do not take grapefruit products while on this therapy as it may increase the side effects of VERZENIO.

Medicines that may reduce the effect of VERZENIO include:

- Carbamazepine, phenytoin (used to treat epilepsy to prevent convulsions, fits).
- Rifampicin (used to treat tuberculosis (TB))
- St. John's wort (a herbal product used to treat mild depression and anxiety).

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

4. How do I use VERZENIO?

How much to take / use

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.
- When given together with endocrine therapy to treat your breast cancer, the recommended dose of VERZENIO is 150 mg orally, twice daily.
- **Swallow the tablet whole with a full glass of water.** Do not chew, crush or split the tablets before swallowing. VERZENIO may be taken with or without food. **Avoid grapefruit products.**

- **Women treated with the combination of VERZENIO plus endocrine therapy should be in a postmenopausal state prior to therapy.**

When to take / use VERZENIO

- **Take your medicine at about the same time each day.**
- Taking it at the same time each day will have the best effect. It ensures that there is enough VERZENIO in your body all the time. It will also help you remember when to take it.
- For early breast cancer your doctor will advise you to take VERZENIO for adjuvant treatment for up to 2 years unless advised otherwise.
- For metastatic breast cancer treatment should be continued until disease progression or unacceptable toxicity. Consult your doctor regarding adverse events.

If you forget to use VERZENIO

VERZENIO should be used regularly at the same time each day. If you miss (vomit) a dose, take your next dose at its scheduled time.

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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much VERZENIO

If you think that you have used too much VERZENIO, 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 VERZENIO?

Things you should do

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

Call your doctor straight away if you:

- become pregnant.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

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

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.

- have diarrhoea

At the first sign of diarrhoea, tell your doctor or pharmacist. Your healthcare provider may tell you to temporarily stop taking VERZENIO, stop your treatment, or decrease your dose. Diarrhoea may cause you to develop dehydration or an infection.

If you have any loose stools, right away tell your healthcare provider, start taking an antidiarrheal medicine (such as loperamide), and drink more fluids.

Things you should not do

- Do not take VERZENIO 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.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- If necessary, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

- **Do not take grapefruit products while on this therapy as it may increase the side effects of VERZENIO.**

Blood tests

- Your doctor will perform a blood test before and during treatment to check whether VERZENIO affects the number of white cells in your blood or the concentration in your blood of enzymes that come from your liver. VERZENIO may reduce the number of white blood cells and produce abnormalities in liver blood tests.

Driving or using machines

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

This medicine may cause fatigue and dizziness in some people. If you experience any symptoms affecting your ability to concentrate and react, do not drive or use machines until the effect goes away.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking this medicine as this medicine may cause fatigue and dizziness in some people.

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.
- Keep your tablets in a cool dry place where the temperature stays 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 sill.

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.

Your doctor may lower your dose or stop treatment temporarily to try to reduce certain side effects while you are taking VERZENIO.

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>Stomach-related:</p> <ul style="list-style-type: none">• diarrhoea• abdominal pain• vomiting• feeling sick (nausea)• constipation• decreased appetite• dry mouth• inflammation of the mouth and lips (stomatitis)• indigestion or upset stomach <p>Skin-related:</p> <ul style="list-style-type: none">• rash• itching• dry skin• hair loss	<p>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"> • red spots or patches on the skin that may look like a target or "bullseye" with a dark red centre surrounded by paler red rings (erythema multiforme) • nail disorders such as breaking or splitting of nails <p>Infection-related:</p> <ul style="list-style-type: none"> • Infections <p>Eye-related:</p> <ul style="list-style-type: none"> • watering eyes <p>Brain related:</p> <ul style="list-style-type: none"> • alteration in sense of taste • dizziness • headache <p>General symptoms:</p> <ul style="list-style-type: none"> • tiredness • inflammation of the lungs which causes breathlessness, cough and raised temperature • muscular weakness 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • flu-like symptoms • fever • decreased weight • swelling in upper and lower limbs (peripheral oedema) <p>Metabolism and nutrition related:</p> <ul style="list-style-type: none"> • decreased appetite • abnormalities in liver blood tests <p>Chest related:</p> <ul style="list-style-type: none"> • cough • shortness of breath 	

Serious side effects

Serious side effects	What to do
<p>General symptoms</p> <ul style="list-style-type: none"> • symptoms that may 	<p>Call your doctor straight away, or go</p>

Serious side effects	What to do
<p>indic low white blood cell coun (neut fever or chills</p> <ul style="list-style-type: none"> • symp that may indic blood clots in your veins Paint swell leg, ches pain, short of breat rapid breat 	<p>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
<p>or rapid heart rate.</p> <ul style="list-style-type: none"> • symptoms that may indicate lung inflammation (pneumonitis): cough, fever, and difficulty breathing or chest discomfort 	

Other side effects you may not be aware of:

- low red blood cell counts (anaemia) which can make you feel lethargic and very tired
- low white blood cell counts which can make you more susceptible to developing infections
- low levels of platelets in blood (thrombocytopenia) which can lead to an increased risk of bleeding or bruising

- low levels of potassium (hypokalaemia) which can lead to feeling tired, leg cramps and weakness
- increased creatinine which can lead to tiredness, swelling and 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.

These side effects may not be fully attributable to VERZENIO alone but may be caused by your condition or by other medicines that you may be taking at the same time.

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 VERZENIO contains

Active ingredient (main ingredient)	abemaciclib
Other ingredients (inactive ingredients)	croscarmellose sodium lactose monohydrate microcrystalline cellulose silicon dioxide sodium stearyl fumarate polyvinyl alcohol (E1203) titanium dioxide (E171) macrogol 3350 (E1521) purified talc (E553b) iron oxide yellow (E172) [50 mg and 150 mg tablets only] iron oxide red (E172) [50 mg tablets only]

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

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes. Contains lactose.

What VERZENIO looks like

VERZENIO is a modified oval immediate-release film coated tablet with “Lilly” debossed on one side and tablet strength in mg debossed on the other.

50 mg tablets are beige in colour (Aust R 304765)

100 mg tablets are white in colour (Aust R 304767)

150 mg tablets are yellow in colour (Aust R 304766)

Who distributes VERZENIO

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

Sydney NSW 2000

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™ = Trademark

If you have any questions about VERZENIO, contact Eli Lilly at 1800 454 559 (Australia) or your healthcare professional for assistance.

This leaflet was prepared in July 2025

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