

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 PIQRAY?

PIQRAY contains the active ingredient Alpelisib. PIQRAY is used with a medicine called fulvestrant to treat certain types of advanced breast cancer in adult women and men.

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

2. What should I know before I use PIQRAY?

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

3. What if I am taking other medicines?

Some medicines may interfere with PIQRAY 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 PIQRAY?

- The usual dose of PIQRAY is 300 mg (two 150 mg film-coated tablets) taken orally, once daily. You should take PIQRAY immediately after food, at approximately the same time each day.

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

5. What should I know while using PIQRAY?

Things you should do	
	• Remind any doctor, dentist or pharmacist

	you visit that you are using PIQRAY. • Have regular blood tests to monitor your condition.
Things you should not do	• Do not stop using this medicine suddenly (unless your doctor tells you to).
Driving or using machines	• PIQRAY has minor influence on the ability to drive and use machines. Be cautious when driving or using machines in case you feel tired with taking PIQRAY.
Drinking alcohol	• There are no known interactions between PIQRAY and alcohol.
Looking after your medicine	• Store below 30°C; protect from moisture.

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

6. Are there any side effects?

Common side effects include painful and frequent wee, tiredness, pale skin, headache, loss of appetite, strange taste in mouth or lack of taste, diarrhoea, nausea, vomiting, tummy pain, indigestion, rash, hair loss/thinning, itching, dry skin, swelling of hands or feet, fever, dry mouth, weight loss, sudden bruising, and cracked lips. 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.

PIQRAY® (PIK-ray)

Active ingredient(s): *Alpelisib* (AL-peh-LIH-sib)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using PIQRAY?

PIQRAY contains the active ingredient alpelisib.
PIQRAY belongs to a class of medicines known as PI3K inhibitors.

PIQRAY is used with a medicine called fulvestrant to treat adult men and women with certain types of advanced breast cancer.

PIQRAY works by blocking the effects of specific enzymes (proteins) that signal cancer cells to grow and multiply. By blocking these enzymes, PIQRAY can decrease cancer cell growth and making new cancer cells, and can also destroy cancer cells.

2. What should I know before I use PIQRAY?

Warnings

Do not use PIQRAY if:

- you are allergic to alpelisib, fulvestrant or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

If you experience an allergic reaction, stop using the medicine and inform your doctor or pharmacist immediately.

Some of the symptoms of an allergic reaction may include:

- Severe itching of the skin, with a red rash, or raised bumps;
- Swelling of the face, lips, tongue, throat, or other parts of the body;
- Difficulty in breathing or swallowing;
- Dizziness.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have any questions about why this medicine has been prescribed for you
- have high levels of sugar in your blood or are having the following symptoms (increased thirst/dry mouth, more frequent wee, feeling tired or sick or increased appetite with weight loss).
- develop a rash, red skin, blistering of the lips, eyes or mouth or skin peeling; with or without fever which may be possible signs of severe skin and tissue 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?](#)

Genetic screening

Before you commence treatment, your tumour tissue or a blood sample will be tested for a particular mutation in a gene called PIK3CA. If the result is positive, PIQRAY is likely to help with your type of breast cancer.

Blood tests before and during your treatment with PIQRAY

Your doctor will carry out blood tests before and regularly during treatment with PIQRAY to monitor your blood sugar. Based on the results, your doctor will take any necessary actions, such as prescribing a medicine to lower blood sugar levels.

- Your doctor will tell you exactly when and where to have the blood tests. You can only start PIQRAY if the blood tests show that you have the right levels of sugar in your blood. This is because PIQRAY can increase sugar in your blood, which could be serious and need treatment. Only regular fasting blood tests can tell the doctor if you are developing high blood sugar levels.
- Your doctor will tell you exactly when and where to test your blood sugar. You will need to have blood sugar tests at least once a week for the first 2 weeks of treatment with Piqray. You will need to have your blood sugar levels checked closely for the first 4 weeks. Afterwards, you will need to have blood tests at least once a month, depending on your blood sugar levels.

Pregnancy and breastfeeding

If you are pregnant, ask your doctor or pharmacist for advice before taking this medicine. PIQRAY may harm an unborn baby and should not be used during pregnancy unless clearly necessary.

If you become pregnant or think you are pregnant, tell your doctor right away.

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

Your doctor will discuss with you the potential risks of taking PIQRAY during pregnancy or breast-feeding. It is not known if PIQRAY passes into your breast-milk.

Do not breast feed during treatment with Piqray and for at least 4 days after the last dose.

Contraception

If you are a woman of child-bearing age, your doctor will check that you are not pregnant, and may perform a pregnancy test if necessary before starting treatment with PIQRAY.

You should avoid becoming pregnant while using Piqray and for at least 4 days after you stop using it. If you are a male you should use a condom if with a female partner that could become pregnant. You should use a condom for at least 4 days after you stop Piqray.

Ask your doctor or pharmacist for options of effective birth control.

Children and adolescents

- PIQRAY is not to be used in children or adolescents under 18 years of age. It is not known whether PIQRAY is safe and effective in children or adolescents.

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 PIQRAY and affect how it works.

- Eltrombopag, a medicine used to treat low platelet count
- Medicines used to treat certain types of breast cancers, such as lapatinib, ribociclib, or everolimus
- Pantoprazole, a medicine used to reduce the amount of acid produced in your stomach (or) heart burn
- Midazolam, a medicine used to make you sleepy or to put you to sleep
- Rifampicin, a medicine used to kill bacteria causing infections
- Encorafenib, a medicine used to treat a certain type of skin cancer
- Warfarin, a medicine used to decrease the clotting of the blood.

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

4. How do I use PIQRAY?

How much to take

- Your doctor will tell you exactly how many tablets of PIQRAY to take.
- Do not exceed the recommended dose prescribed by your doctor.
- The usual starting dose of PIQRAY is 300 mg (two PIQRAY 150 mg tablets) once daily.
- Depending on how your body responds to the treatment with PIQRAY, your doctor may adjust your dosage. It is very important to follow your doctor's recommendations.
- If you have certain side effects your doctor may change your dose to a lower dose or ask you to skip the dose or to stop treatment.

When to take PIQRAY

- Take PIQRAY once a day, every day; at the same time, immediately after food.

How to take PIQRAY

- Always take PIQRAY exactly as your doctor or pharmacist has told you. Your doctor or pharmacist

will tell you exactly how many tablets to take and which days to take them on.

- If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.
- Swallow PIQRAY tablets whole with a glass of water or other liquid.
- Do not chew, crush, or split the tablets before swallowing.
- PIQRAY tablets should not be taken if broken or cracked.
- If you vomit after you swallow the tablets, do not take any more PIQRAY tablets until your next scheduled dose (tomorrow).

Do not change the PIQRAY dose or schedule without talking to your doctor.

How long to take PIQRAY

- Take PIQRAY for as long as your doctor tells you to.

If you forget to use PIQRAY

If you forget to take PIQRAY, you may still take it, immediately after food, up to 9 hours after the time you normally take it.

If you remember more than 9 hours after you normally take your PIQRAY, skip the dose for that day. The next day, take the dose at your usual time.

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 when to take or skip PIQRAY, keep a treatment diary, or ask your doctor, nurse or pharmacist for some hints.

If you use too much PIQRAY

If you think that you have accidentally taken too many tablets you may need 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.

Take the PIQRAY pack with you. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

5. What should I know while using PIQRAY?

Things you should do

- Have regular blood tests as directed by your doctor to monitor your blood sugar and general wellbeing
- Keep all doctor's appointments, as your doctor needs to regularly monitor your condition

Call your doctor straight away if you:

- Become pregnant or think you might be pregnant
- Think you might be having an allergic reaction to PIQRAY treatment
- Are experiencing a rash, red skin, blistering of the lips, eyes or mouth or skin peeling; with or without fever which may be possible signs of severe skin and tissue condition.
- Experience diarrhoea, or if you experience severe tummy pain or stools with mucus or blood, which may be signs of inflammation of your intestine (colitis).
- Experience new or changing respiratory problems including difficult or painful breathing, cough, rapid breathing, pain in chest while breathing, blue discoloration of the lips, tongue or skin, or hiccups, which may be signs of non-infectious pneumonitis and pneumonia.

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

Things you should not do

- **Do not stop using this medicine suddenly unless your doctor tells you to.**
- **Do not give this medicine to anyone else. Even if they have the same condition as you.**

Use in high blood sugar

- Your doctor may decrease your PIQRAY dose for a short time to allow your blood sugar levels to improve or may stop treatment permanently.

Driving or using machines

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

PIQRAY may cause tiredness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

There are no known interactions of PIQRAY with alcohol.

Looking after your medicine

- Store below 30°C

Follow the instructions on 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.

When to discard your medicine

If your doctor tells you to stop taking PIQRAY or the tablets have passed their use by (expiry date).

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
Tummy problems: • Stomach pain • Vomiting • Feeling sick • Diarrhoea	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• Indigestion • Loss of appetite Eye problems: • Dry eye • Blurred vision Skin problems: • Rash • Hives • Itching • Swelling Mouth problems: • Bleeding or sore gums • Dryness • Mouth sores/ulcers • Toothache General: • Swollen hands, ankles or feet • Swelling and/or reddening of arms, legs, hands and feet • Painful/frequent wee • Tiredness • Difficulty sleeping • Headache	If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Less serious side effects	What to do
• Dizziness • Muscle pain/spasms • Muscle weakness or cramps • Hair thinning • Strange taste in the mouth or lack of taste • Sudden bleeding or bruising • Pain, swelling or numbness of the jaw	

Serious side effects

Serious side effects	What to do
Lung problems: • Difficulty breathing • Facial, throat swelling • Light-headedness • Change in colour (blue) of the tongue or lips Skin problems: • Rash, itching, hives, reddening	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.

Serious side effects	What to do
• Blisters on lips, eyes or mouth • Skin peeling • Flushed skin Kidney problems: • Unexplained increased or decreased amount of wee • Increased appetite with weight loss • Swelling in legs, ankles, around the eyes • Fruity smell on breath Tummy problems: • Severe abdominal pain • Blood or mucus in stools	

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 can only be found when your doctor does tests from time to time to check your progress.

These include:

- Higher levels of liver enzymes
- Changes to your blood cell counts
- Changes to your blood electrolyte levels.

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 PIQRAY contains

Active ingredient (main ingredient)	Alpelisib
Other ingredients (inactive ingredients)	Microcrystalline cellulose (E460(i)) Mannitol (E421) Sodium starch glycolate Hyprolose (E463)

	Magnesium stearate (vegetable source) (E572) Macrogol (E1521) Titanium dioxide (E171) Iron oxide black CI77499 (E172) Iron oxide red CI77491 (E172) Purified talc (E553b)
Potential allergens	PIQRAY does not contain sucrose, lactose, tartrazine, azo dyes, or any animal products.

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

What PIQRAY looks like:

PIQRAY is supplied as film coated tablets in aluminium blisters.

Piqray alpelisib 300 mg blister (2 x 150mg film coated tablet) - **AUST R 315064.**

This pack is for patients taking the alpelisib daily dose of 300 mg (as two 150 mg tablets) once daily.

Piqray alpelisib 250 mg blister (200mg + 50mg film coated tablet) - **AUST R 315055 .**

This pack is for patients taking a reduced alpelisib daily dose of 250 mg (as one 200 mg tablet plus one 50 mg tablet) once daily.

Piqray alpelisib 200 mg film coated tablet blister pack -
AUST R 315020.

This pack is for patients taking the lowest alpelisib daily dose of 200 mg.

PIQRAY 50 mg tablet:

Light pink, unscored, round and curved with bevelled edges film-coated tablet, imprinted with "L7" on one side and "NVR" on the other side.

Each film coated tablet contains 50 mg of alpelisib

PIQRAY 150 mg tablet:

Pale red, unscored, ovaloid and curved with bevelled edges film-coated tablet, imprinted with "UL7" on one side and "NVR" on the other side.

Each film coated tablet contains 150 mg of alpelisib.

PIQRAY 200 mg tablet:

Light red, unscored, ovaloid and curved with bevelled edges film-coated tablet, imprinted with "YL7" on one side and "NVR" on the other side.

Each film coated tablet contains 200 mg of alpelisib.

Who distributes PIQRAY

PIQRAY is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160
Level 25, Victoria Cross Tower
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www.novartis.com.au

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