

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 Perjeta?

Perjeta contains the active ingredient pertuzumab. Perjeta is used to treat the following stages of breast cancer;

- metastatic (spreading) breast cancer
- early breast cancer, either before or after surgery

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

2. What should I know before I use Perjeta?

Do not use if you have ever had an allergic reaction to pertuzumab 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.

Tell your doctor if you have previously been treated with chemotherapy medicines known as anthracyclines (e.g. doxorubicin); these medicines can damage heart muscle and increase the risk of heart problems with Perjeta.

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

3. What if I am taking other medicines?

Some medicines may interfere with Perjeta 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 is Perjeta given?

- Perjeta must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.
- Perjeta is given by a drip into a vein (intravenous (IV) infusion) once every three weeks.
- The amount of medicine you are given, and how long the infusion will last, are different for the first and following doses.

More instructions can be found in Section [4. How is Perjeta given?](#) in the full CMI.

5. What should I know while using Perjeta?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Perjeta.• Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reaction• Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine without speaking to your doctor first.• Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.
Pregnancy	<ul style="list-style-type: none">• Do not take Perjeta if you are pregnant.• Tell your doctor if you become pregnant or intend to start a family while receiving Perjeta or within 7 months after your last Perjeta treatment.

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

6. Are there any side effects?

Tell your doctor or nurse immediately or seek immediate medical attention if you experience; severe or persistent diarrhoea, signs or symptoms of a serious allergic reaction (including shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body and rash, itching or hives on the skin) and/or signs or symptoms of heart problems (including shortness of breath or getting tired easily after light physical activity (such as walking), shortness of breath at night, especially when lying flat, swelling of the hands or feet due to fluid buildup, cough and/or abnormal or irregular heartbeat).

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

Perjeta®

Active ingredient(s): *pertuzumab (rch)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Perjeta?

Perjeta contains the active ingredient pertuzumab.

Perjeta belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents. There are many different classes of anti-neoplastic agents. Perjeta belongs to a class called monoclonal antibodies.

Monoclonal antibodies are proteins made in a laboratory. These proteins are designed to recognise and bind to other unique proteins in the body.

Perjeta recognises and attaches to a protein called human epidermal growth factor receptor 2 (HER2). HER2 is found in large amounts on the surface of some cancer cells. When Perjeta attaches to HER2 cancer cells it may kill them or slow/stop the cancer cells from growing.

Perjeta is used to treat the following stages of breast cancer;

- **metastatic (spreading) breast cancer**
- **early breast cancer, either before or after surgery**

It is only used for patients whose tumour has tested positive for HER2.

For metastatic breast cancer, Perjeta is used with trastuzumab and the chemotherapy medicine, docetaxel. For early breast cancer, Perjeta is used with trastuzumab and chemotherapy medicines.

For further information about trastuzumab and other chemotherapy medicines please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) leaflets for these medicines.

Ask your doctor if you have any questions why Perjeta has been prescribed for you.

2. What should I know before I use Perjeta?

Warnings

If you are not sure if you should start receiving Perjeta, talk to your doctor.

Do not use Perjeta if:

- you are allergic to pertuzumab, 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 are pregnant
- if the package is torn or shows signs of tampering
- if the expiry date (EXP) printed on the pack has passed
- If you take this medicine after the expiry date has passed it may not work as well.

Check with your doctor if you:

- **you have a history of heart problems such as;**
 - heart failure (where the heart muscle cannot pump blood strongly enough)
 - cardiac arrhythmias (abnormal beating of the heart)
 - poorly controlled high blood pressure or
 - recent heart attack
- **you have previously been treated with chemotherapy medicines known as anthracyclines (e.g. doxorubicin);** these medicines can damage heart muscle and increase the risk of heart problems with Perjeta
- **you have ever had heart problems during previous treatment with trastuzumab.** Your doctor will monitor your heart function closely before, and during your treatment with Perjeta.
- **you have inflammation of the digestive tract, for e.g. sore mouth or diarrhoea.** When Perjeta is given with other cancer treatments, the number of white blood cells may drop and fever may develop. If you have inflammation of the digestive tract (e.g sore mouth or diarrhoea), you may be more likely to develop this side effect
- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes.** Allergic or anaphylactic (more severe allergic) reactions can occur with Perjeta treatment (known as infusion related reactions). Your doctor or nurse will check for side effects during your infusion and for 30 - 60 minutes afterwards. If you get any serious reactions, your doctor may stop treatment with Perjeta. See Section 6. Are there any side effects? for symptoms to look out for.

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

Do not use Perjeta if you are pregnant. Perjeta may be harmful to your unborn baby.

Your doctor will advise you about using effective contraception to avoid becoming pregnant while you are being treated with Perjeta and for 7 months after stopping treatment.

Tell your doctor right away if you become pregnant during treatment with Perjeta.

Breastfeeding

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

It is not known if Perjeta passes into breast milk.

Use in children

The safety and effectiveness of Perjeta in children and adolescents under 18 years of age 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. These may affect Perjeta.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving Perjeta.

4. How is Perjeta given?

Follow all directions given to you by your doctor or nurse carefully. They may differ from the information contained in this leaflet.

Perjeta must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

Perjeta is given by a drip into a vein (intravenous (IV) infusion) once every three weeks.

The amount of medicine you are given, and how long the infusion will last, are different for the first and following doses.

The number of infusions you will be given depends on how you respond to treatment.

Perjeta is given with other anti-cancer medicines.

The first infusion:

You will be given 840 mg of Perjeta by IV drip over 60 minutes. You will also be given trastuzumab and chemotherapy medicines.

For following infusions:

If the first infusion was well tolerated, you will be given 420 mg of Perjeta by IV drip over 30 - 60 minutes. You will also be given trastuzumab and chemotherapy medicines.

For further information about the dose of other anti-cancer medicines given, please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) leaflets for these medicines.

If you miss a dose of Perjeta

As Perjeta is given under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive Perjeta, do not wait until the next planned infusion but make another appointment as soon as possible. Your doctor will decide when and how much your next dose of Perjeta will be.

If it has been 6 weeks or more since your last Perjeta treatment, the high dose of Perjeta (840 mg) will be given. You will also be given trastuzumab and docetaxel.

If you use too much Perjeta

As Perjeta is given under the supervision of your doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given Perjeta, tell your doctor immediately.

5. What should I know while using Perjeta?

Things you should do

Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reaction. Some of the 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
- feeling sick (nausea), fever or chills
- feeling tired or headache

Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems.

Some signs or symptoms of heart problems are:

- shortness of breath or getting tired easily after light physical activity (such as walking)
- shortness of breath at night, especially when lying flat
- swelling of the hands or feet due to fluid build up
- cough
- abnormal or irregular heartbeat

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

- Your doctor may perform regular tests.

Tell your doctor as soon as possible if you do not feel well while you are receiving Perjeta.

Tell your doctor if you feel that Perjeta is not helping your condition.

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

Things you should not do

Do not stop your Perjeta treatment without talking to your doctor first.

Driving or using machines

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

It is not known whether Perjeta may impair your ability to drive or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Perjeta will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Perjeta may have some unwanted side effects in some people.

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.

Ask your doctor or pharmacist to answer any questions you may have or you do not understand anything in this list.

Because Perjeta may be used with other medicines that treat breast cancer, it may be difficult for your doctor to tell whether the side effects are due to Perjeta or due to the other medicines.

For further information about the side effects of trastuzumab and chemotherapy, please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) leaflets for these medicines.

Serious side effects

Serious side effects	What to do
<p>During an infusion:</p> <ul style="list-style-type: none"> swelling of your face, lips, tongue or throat with difficulty breathing, swelling of other parts of your body such as your hands or feet shortness of breath, wheezing or trouble breathing abnormal or irregular heartbeat rash, itching or hives on the skin feeling sick (nausea) diarrhoea fever or chills headache fatigue or tiredness cough 	<p>Tell your doctor or nurse immediately if you notice any of the following while receiving an infusion (particularly during the first infusion).</p> <p>These may be serious side effects. You may require urgent medical attention.</p>
<p>After an infusion:</p> <ul style="list-style-type: none"> severe or persistent diarrhoea. swelling of your face, lips, tongue or throat with difficulty breathing, severe swelling of your hands or feet severe shortness of breath, wheezing or trouble breathing severe chest pain, spreading out to the arms, neck, shoulder or back abnormal or irregular heartbeat rash, itching or hives on the skin fever or chills severe coughing 	<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>

Less serious side effects

Less serious side effects	What to do
<p>After an infusion:</p> <ul style="list-style-type: none"> any of the side effects listed above constipation indigestion or stomach pain sore mouth, throat or gut 	<p>Tell your doctor or nurse as soon as possible if you notice any of these.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> getting tired more easily after light physical activity such as walking shortness of breath especially when lying down or being woken from your sleep with shortness of breath nail problems especially inflammation where the nail meets the skin hair loss feeling dizzy, tired, looking pale hot flushes frequent infections such as fever, severe chills, sore throat or mouth ulcers nose bleeds eye problems such as producing more tears insomnia (trouble sleeping) weak, numb, tingling, prickling or painful sensations mainly affecting the feet and legs loss of appetite, loss of or altered taste joint or muscle pain, muscle weakness 	

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Others may occur in some people and there may be some side effects not yet known.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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 Perjeta contains

Active ingredient (main ingredient)	Each vial of Perjeta contains 420 mg of the active ingredient pertuzumab The pertuzumab protein is made using Chinese hamster ovary cells.
Other ingredients (inactive ingredients)	glacial acetic acid histidine sucrose

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

What Perjeta looks like

Perjeta is a clear to pearly (opalescent), colourless to slightly brownish solution.

Perjeta is supplied as a single-dose glass vial containing 14 mL of solution for intravenous infusion (30 mg/mL). It is diluted before infusion into a vein. (Aust R 196218).

Who distributes Perjeta

Perjeta is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney, NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information (CMI).

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