

Perjeta®

Contains the active ingredient pertuzumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Perjeta. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Perjeta against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Perjeta is given for

Perjeta contains an active ingredient called 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 Herceptin and the chemotherapy medicine, docetaxel. For early breast cancer Perjeta is used with Herceptin and chemotherapy medicines.

For further information about Herceptin 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.

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

Before you are given Perjeta

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

When you must not be given Perjeta

Do not use Perjeta:

- **if you have had an allergic reaction to Perjeta or any of the ingredients listed at the end of this leaflet**

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
- **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.

Before you are given it

Tell your doctor if:

- **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 Herceptin**

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 "side effects" for symptoms to look out for.

- **you are pregnant or intend to become pregnant**

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.

- **you are breast-feeding or plan to breast-feed**

It is not known if Perjeta passes into breast milk. You should talk to your doctor about whether you can breast feed while you are being treated with Perjeta.

If you have not told your doctor about any of the above, tell them before you are given Perjeta.

Use in children

The safety and effectiveness of Perjeta in children and adolescents under 18 years of age have not been established.

Taking other medicines

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

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

How Perjeta is 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 Herceptin 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

Herceptin 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

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, make another appointment as soon as possible.

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 Herceptin and docetaxel.

Your doctor will decide when and how much your next dose of Perjeta will be.

If you are given too much (overdose)

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.

While you are receiving Perjeta

Things you must do

Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reaction

Some signs and symptoms include;

- swelling of your face, lips, tongue or throat with difficulty breathing,
- swelling of other parts of your body
- shortness of breath, wheezing or trouble breathing
- rash, itching or hives on the skin

- feeling sick (nausea)
- fever, chills
- feeling tired
- headache

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

Some signs and 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

Please follow all your doctors' instructions if any of these symptoms require medication.

Tell your doctor or nurse immediately if you develop severe or persistent diarrhoea.

Tell all doctors, dentists and pharmacists who are treating you, that you are receiving Perjeta.

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.

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

Your doctor may perform regular tests.

Things you must not do

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

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

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Perjeta affects you.

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

Side effects

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

Perjeta may have some unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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 Herceptin and chemotherapy, please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) leaflets for these medicines.

During an infusion

Tell your doctor or nurse immediately if you notice any of the following while receiving an infusion (particularly during the first infusion):

- 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

These may be serious side effects. You may need medical attention.

After an infusion

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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

Tell your doctor or nurse as soon as possible if you notice any of the following:

- any of the side effects listed above
- diarrhoea or constipation
- indigestion or stomach pain
- sore mouth, throat or gut
- 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 if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor, nurse or pharmacist if you don't understand anything in this list.

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

Product description

Storage

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

Availability

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.

What PERJETA looks like

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

Ingredients

Each vial of Perjeta contains 420 mg of the active ingredient pertuzumab

It also contains:

- glacial acetic acid
- histidine
- sucrose
- polysorbate 20

The pertuzumab protein is made using Chinese hamster ovary cells.

Distributor

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).

Australian Registration Number:

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