PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Perjeta®concentrate for solution for infusion 30 mg/mL

The active substance is pertuzumab

Contains sugar

Read all of this leaflet carefully before you start receiving Perjeta

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.

What is in this leaflet

1. What Perjeta is and what it is used for
2. What you need to know before you are given Perjeta
3. How you are given Perjeta
4. Possible side effects
5. How to store Perjeta
6. Contents of the pack and other information

1. What Perjeta is and what it is used for

Perjeta is used to treat people with breast cancer when:

- The breast cancer has been identified to be of the “HER2-positive” form – your doctor will test you for this.
- The cancer has spread to other parts of the body (metastasised) and has not previously been treated with anticancer medicines (chemotherapy) or other medicines designed to attach to HER2, or else the cancer has come back in the breast after previous treatment.

- The cancer has not spread to other parts of the body and treatment will be given before surgery takes place (treatment before surgery is called neoadjuvant therapy).
- Early stage breast cancer.
- The cancer has not spread to other parts of the body and treatment is going to be given after surgery (treatment after surgery is called adjuvant therapy).

As well as Perjeta you will also receive trastuzumab and other chemotherapy medicines. If you receive Perjeta before or after surgery, you may also receive other chemotherapy as part of your overall treatment. Information about these medicines is described in their separate patient information leaflets. Ask your doctor or nurse to give you information about these medicines.

How Perjeta works

Perjeta is a type of medicine called a “monoclonal antibody” which attaches itself to specific targets in your body. Perjeta recognises and attaches to a target in your body called “human epidermal growth factor 2” or HER2 for short. HER2 is found in large amounts on the surface of some cancer cells where it stimulates their growth. When Perjeta attaches to the HER2 cancer cells, it may slow or stop the cancer cells from growing.

2. What you need to know before Perjeta is administered to you

You should not receive Perjeta

- If you are allergic to pertuzumab or to any of the other ingredients of this medicine, listed in “What Perjeta contains”. If you are not sure, talk to your doctor or nurse before you receive Perjeta.
- If you are pregnant or are breastfeeding your baby.

Warnings and precautions

Talk to your doctor or healthcare professional before you receive Perjeta if:

- You have ever had heart problems (such as heart failure, treated for serious irregular heartbeats, uncontrolled high blood pressure, recent heart attack) – your doctor will run tests to check if your heart is working properly.
- You have ever had heart problems during previous treatment with trastuzumab.
- You have ever had a chemotherapy medicine from a class called anthracyclines, e.g. doxorubicin or epirubicin – these medicines can damage heart muscle and increase the risk of heart problems with Perjeta.

If any of the above applies to you (or if you are not sure), talk to your doctor or nurse before you receive Perjeta.

Infusion-related reactions:

Infusion-related reactions, allergic or anaphylactic reactions (more severe allergic reactions) can happen. Your doctor or nurse will check for side effects during your infusion and for 30 to 60 minutes afterwards. If you get any serious reaction, your doctor may stop treatment with Perjeta. Some patients have died due to anaphylactic reactions during a Perjeta infusion. See “Serious side effects” for more details about infusion associated reactions to look out for during the infusion and thereafter.

Heart problems:

Treatment with Perjeta may affect your heart. Therefore, your heart function will be checked before and during treatment with Perjeta. See “Serious side effects” for more details about signs of heart problems to look out for.

Febrile neutropenia (Low white blood cells with fever):

The number of your 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.

Diarrhoea:

Treatment with Perjeta may cause severe diarrhoea. Diarrhoea is a condition where your body produces more-watery stools than normal. If you experience severe diarrhoea while receiving

your anti-cancer treatment, your doctor may start you on anti-diarrhoeal treatment and may stop treatment with Perjeta until the diarrhoea is under control.

Use in the elderly

If you are older than 65 years of age, you are more likely to experience side effects such as reduced appetite, decrease in the number of red blood cells, weight loss, feeling tired, loss or altered taste, weak, numb, tingling or prickling sensations mainly affecting the feet and legs and diarrhoea, compared to patients who younger than 65 years of age.

Use in children and adolescents:

Perjeta is not recommended if you are under 18 years of age because there is no information on how well it works in this age group.

Other medicines and Perjeta

If you are taking/using medicines on a regular basis, including complementary or traditional medicines, the use of Perjeta with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

It may take up to 6 months for Perjeta to be removed from the body. Therefore you should tell your doctor that you have had Perjeta if you start any new medication in the 6 months after stopping treatment.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Pregnancy and Breastfeeding

Women receiving Perjeta must not become pregnant and women whose partners are receiving Perjeta must not become pregnant.

Before starting treatment, you must tell your doctor or healthcare professional if you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby.

Tell your doctor straight away, if you become pregnant during treatment with Perjeta or during the 6 months after stopping treatment.

Perjeta may harm your unborn baby. You should use effective contraception during treatment with Perjeta and for 6 months after stopping treatment. Talk to your doctor about the best contraception for you.

If a male patient is receiving Perjeta, his female partner must not become pregnant, nor for 6 months after stopping Perjeta. Effective contraception must be used.

Women should not breastfeed their babies while receiving Perjeta.

Driving and using machines

If you experience headaches, dizziness or infusion reactions, it is advisable that you do not drive nor use machines until symptoms subside.

Perjeta contains sucrose

If you have an allergy/intolerance to sugars, please consult your doctor for advice.

Perjeta contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Perjeta.

3. How Perjeta is given

Perjeta must always be administered by a doctor.

Receiving Perjeta

Your doctor will tell you how long treatment with Perjeta will last.

Perjeta will be given to you by a doctor or healthcare professional in a hospital or clinic.

- Perjeta is given as a drip into your vein (intravenous infusion) once every three weeks.

- The amount of Perjeta you are given and how long the infusion will last are different for the first, second and following doses.
- The number of infusions you are given depends on how you respond to treatment and whether you are receiving treatment before or after surgery (neoadjuvant or adjuvant therapy) or for disease which has spread.
- Perjeta is given with other cancer treatments (trastuzumab and chemotherapy), over 60 minutes for the first infusion or 30 - 60 minutes for following infusions.

For further information on trastuzumab and chemotherapy (both of which can cause side effects as well), please refer to the patient information leaflets for these products in order to understand the use of these medications. If you have questions about these medications, please ask your doctor.

If you have the impression that Perjeta is too strong or too weak, talk to your doctor or pharmacist.

If you take more Perjeta than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of Perjeta

If you forget or miss your appointment to receive Perjeta make another appointment as soon as possible. If this has been 6 weeks or more since your last visit: a higher Perjeta dose may be given.

Effects when treatment with Perjeta is stopped

Do not stop your Perjeta treatment without talking to your doctor first. If you have any further questions on the use of Perjeta talk to your doctor or nurse.

4. Possible side effects

Perjeta can cause side effects.

Not all side effects reported for Perjeta are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Perjeta, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side effects - *Tell your doctor or nurse straight away, if you notice any of the following side effects:*

- Infusion associated, allergic and anaphylactic reactions can happen. These include swelling of your face and throat with difficulty breathing, feeling sick (nausea), fever, chills, feeling tired, headache, loss of appetite, constipation and mouth ulcers.
- Symptoms of heart problems (heart failure) can include cough, shortness of breath when sleeping flat and swelling (fluid retention) in your legs and arms.
- Tumour lysis syndrome (a condition which may happen when cancer cells die quickly, causing changes in the blood levels of minerals and metabolites shown in a blood test). Symptoms may include kidney problems (weakness, shortness of breath, fatigue and confusion), heart problems, fluttering of the heart or a faster or slower heartbeat), seizures, vomiting or diarrhoea and tingling in the mouth, hands or feet.
- The most common side effects are diarrhoea, hair loss, and a decrease in the number of your white blood cells with or without fever (shown in a blood test).

Tell your doctor or nurse immediately if you notice any of the side effects listed above.

Other side effects include:

Frequent:

- Feeling dizzy
- shortness of breath
- fever
- producing more tears

- not being able to sleep
- decrease in the number of red blood cells – shown in a blood test
- sore throat
- red, sore or runny nose
- flu-like symptoms and a fever
- weak, numb, tingling or pricking sensations mainly affecting the feet and legs
- nail problems
- loss or altered taste
- feeling sick or being sick
- having less of an appetite
- rash, dry, itchy or acne like skin
- joint or muscle pain
- muscle weakness
- inflammation of the lining of your mouth (stomatitis) and gut
- swollen ankles or other areas of your body due to your body holding onto too much water
- nose bleeds
- hot flushes
- stomach ache
- pain in the lower parts of your body
- Swelling in your legs
- fluid retention in your body, causing swelling

Less frequent:

- Fluid on the lungs causing difficulty in breathing;
- inflammation of the nail bed where the nail and skin meet;
- condition in which the left ventricle of the heart is functionally impaired with or without symptoms.

If you experience any of the above symptoms after treatment with Perjeta has been stopped, you should consult your doctor immediately and inform him/her that you have previously been treated with Perjeta.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Perjeta.

5. How to store Perjeta

Store all medicines out of reach of children.

Do not freeze. Do not shake.

Keep vial in the outer carton in order to protect from light until required for use.

Perjeta will be stored by the healthcare professionals at the hospital or clinic, in a refrigerator between 2 °C - 8 °C.

A sterile needle and syringe should be used to prepare the diluted infusion solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Perjeta contains

The active substance is pertuzumab. Each vial contains 420 mg pertuzumab. Each vial of Perjeta contains 420 mg pertuzumab in 14 mL preservative free concentrate, (equivalent to 30 mg/mL), concentrated solution for infusion.

The other ingredients are: Glacial acetic acid l-histidine, polysorbate 20, sucrose and water for injections.

Contains sugar (sucrose).

What Perjeta looks like and contents of the pack

Perjeta is a sterile almost clear to slightly opalescent, colourless to pale yellow liquid which contains no preservatives.

Perjeta is presented as a colourless glass vial, sealed with a grey butyl rubber stopper and crimped with a silver aluminium cap fitted with a pink flip-off plastic disc. Pack of 1 vial in a carton.

Holder of Certificate of Registration

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park

Building E, Vorna Valley

Midrand, Johannesburg, 1686

South Africa

Roche Ethical Assistance Line toll-free: 0800 21 21 25

This leaflet was last revised on: 27 August 2022

Registration date: 18 October 2022

Registration number

48/30.1/0370

Namibia: NS2 19/26/0032
Botswana: NS2 BOT2103721
Zimbabwe:NS2 2019/9.7/5926