Package Leaflet: Information for the user

Perjeta 420 mg concentrate for solution for infusion
pertuzumab

Read all of this leaflet carefully before you start being given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Perjeta is and what it is used for

Perjeta contains the active substance pertuzumab and is used to treat adult patients 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 such as the lungs or liver (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 is going to be given before surgery takes place (treatment before surgery is called neoadjuvant therapy)
- 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 medicines called chemotherapy Information about these medicines is described in separate package leaflets. Ask your doctor or nurse to give you information about these other medicines.

How Perjeta works

Perjeta is a type of medicine called a "monoclonal antibody" which attaches itself to specific targets in your body and on the cancer cells.

Perjeta recognises and attaches to a target called "human epidermal growth factor receptor 2" (HER2). 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, or may kill them.

2. What you need to know before you are given Perjeta

You must not be given Perjeta

- If you are allergic to pertuzumab, or to any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or nurse before you are given Perjeta.

Warnings and precautions

Treatment with Perjeta may affect the heart. Talk to your doctor or nurse before you are given Perjeta:

- If you have ever had heart problems (such as heart failure, treatment for serious irregular heartbeats, uncontrolled high blood pressure, recent heart attack), your heart function will be checked before and during treatment with Perjeta and your doctor will run tests to check if your heart is working properly.
- If you have ever had heart problems during previous treatment with trastuzumab.
- If you have ever had a chemotherapy medicine from the 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 you are not sure), talk to your doctor or nurse before you are given Perjeta. See section 4 "Serious side effects" for more details about signs of heart problems to look out for.

Infusion reactions
Infusion reactions, allergic or anaphylactic (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. Very rarely, patients have died due to anaphylactic reactions during Perjeta infusion. See section 4 "Serious side effects" for more details about infusion reactions to look out for during the infusion and thereafter.

Febrile neutropenia (Low white blood cells with fever)
When Perjeta is given with other cancer treatments (trastuzumab and chemotherapy), the number of white blood cells may drop and fever (raised temperature) 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. Patients over 65 years of age have a higher risk of diarrhoea compared with patients younger than 65 years of age. 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 your treatment with Perjeta until the diarrhoea is under control.

Use in children and adolescents
Perjeta should not be given to patients under the age of 18 years because there is no information on how it works in this age group.

Use in the elderly
Patients over 65 years of age who are treated with Perjeta 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 younger than 65 years of age.

Other medicines and Perjeta
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
Before starting treatment, you must tell your doctor or nurse if you are pregnant or breast-feeding, or if you think you may be pregnant or are planning to have a baby. They will advise you about the benefits and risks for you and your baby of taking Perjeta while you are pregnant.

- Tell your doctor straight away, if you get pregnant during treatment with Perjeta or during the 6 months after stopping treatment.
- Ask your doctor about whether you can breast-feed during or after treatment with Perjeta.

Perjeta may harm the 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.

Driving and using machines
Perjeta may have a minor effect on you being able to drive or use machines. However, if you get any dizziness, infusion reactions, allergic or anaphylactic reactions, wait until these have gone away before driving or using machines.

Sodium
Perjeta contains less than 1 mmol of sodium per dose, i.e. it is essentially sodium-free.

3. How you are given Perjeta

Being given this medicine

Perjeta will be given to you by a doctor or nurse in a hospital or clinic.
- It is given by a drip into a vein (intravenous infusion) once every three weeks.
- The amount of medicine you are given and how long the infusion will last are different for the first dose and following doses.
- The number of infusions you will be 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).

For the first infusion:
- You will be given 840 mg of Perjeta over 60 minutes. Your doctor or nurse will check for side effects during your infusion and for 60 minutes afterwards.
- You will also be given trastuzumab and chemotherapy.

For all following infusions, if the first infusion was well tolerated:
- You will be given 420 mg of Perjeta over 30 to 60 minutes. Your doctor or nurse will check for side effects during your infusion and for 30 to 60 minutes afterwards.
- You will also be given trastuzumab and chemotherapy.

For further information on dosing of trastuzumab and chemotherapy (which can cause side effects as well), please refer to the package leaflet for these products. If you have questions about these medicines, please ask your doctor or nurse.

If you forget to have Perjeta
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 visit a higher Perjeta dose of 840 mg will be given to you.

If you stop having Perjeta
Do not stop having this medicine without talking to your doctor first. It is important that you are given all the infusions that have been recommended.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Tell a doctor or nurse straight away, if you notice any of the following side effects:
- Very severe or persistent diarrhoea (7 or more stools per day).
- A decrease in the number or low amount of white blood cells (shown in a blood test), with or without fever, which may increase the risk of an infection.
- Infusion reactions with symptoms that can either be mild or more severe and may include feeling sick (nausea), fever, chills, feeling tired, headache, loss of appetite, joint and muscle pains, and hot flushes.
- Allergic and anaphylactic (more severe allergic) reactions with symptoms that may include swelling of your face and throat, with difficulty in breathing. Very rarely, patients have died due to anaphylactic reactions during Perjeta infusion.
- Heart problems (heart failure) with symptoms that can include cough, shortness of breath, and swelling (fluid retention) in your legs or arms.
- Tumour lysis syndrome (a condition which may happen when cancer cells die quickly, causing changes in 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 at a faster or slower heartbeat), seizures, vomiting or diarrhoea and tingling in the mouth, hands or feet

Tell a doctor or nurse straight away, if you notice any of the side effects above.

Other side effects include:

Very common (may affect more than 1 in 10 people):
- Diarrhoea
- Hair loss
- Feeling sick or being sick
- Feeling tired
- Rash
- Inflammation of your digestive tract (e.g. sore mouth)
- Decrease in the number of red blood cells – shown in a blood test
- Joint or muscle pain, muscle weakness
- Constipation
- Reduced appetite
- Loss of or altered taste
- Fever
- Swollen ankles or other body parts due to your body retaining too much water
- Not being able to sleep
- Hot flushes
- Weak, numb, tingling or prickling sensations mainly affecting the feet and legs
- Nose bleeds
- Cough
- Heartburn

- Dry, itchy or acne like skin
- Nail problems
- Sore throat, red, sore or runny nose, flu-like symptoms and fever
- Producing more tears
- Fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- Pain in the body, arms, legs, and belly
- Shortness of breath
- Feeling dizzy

Common (may affect up to 1 in 10 people):
- A feeling of numbness, prickling or tingling in feet or hands; sharp jabbing, throbbing, freezing or burning pain; feeling pain from something which should not be painful such as a light touch; less able to feel changes in heat or cold; loss of balance or coordination
- Inflammation of the nail bed where the nail and skin meet
- Infection of the ear, nose or throat
- Condition in which the left ventricle of the heart is functionally impaired with or without symptoms

Uncommon (may affect up to 1 in 100 people):
- Chest symptoms such as a dry cough or breathlessness (possible signs of interstitial lung disease, a condition of damage to the tissues around the air sacs in the lungs)
- Fluid around the lungs causing difficulty in breathing

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

Some of the side effects which you get may be due to your breast cancer. If you are given Perjeta with trastuzumab and chemotherapy at the same time, some side effects may also be due to these other medicines.

Reporting of side effects
If you get any 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 directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Perjeta

Perjeta will be stored by the health professionals at the hospital or clinic. The storage details are as follows:
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the outer carton after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C).
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light.
- Do not use this medicine if you notice any particles in the liquid or it is the wrong colour (please see section 6).

- 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 a total of 420 mg pertuzumab at a concentration of 30 mg/ml
- The other ingredients are glacial acetic acid, L-histidine, sucrose, polysorbate 20 and water for injections

What Perjeta looks like and contents of the pack
Perjeta is a concentrate for solution for infusion. It is a clear to slightly pearly (opalescent), colourless to pale yellow liquid. It is supplied in a glass vial containing 14 ml concentrate.
Each pack contains one vial.

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