PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Herceptin® 21 mg/ml IV Infusion

Bacteriostatic Water for Injection for Herceptin® Diluent for injection

Read all of this leaflet carefully before you start receiving Herceptin 21 mg/ml IV

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Herceptin 21 mg/ml IV has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT HERCEPTIN 21 mg/ml IV CONTAINS

Herceptin 21 mg/ml IV contains 21 mg trastuzumab per ml.

Herceptin 21 mg/ml IV contains the excipients αα-trehalose, l-histadine, polysorbate 20 and water for injection.

Bacteriostatic Water for Injection for Herceptin: The solvent for reconstitution of Herceptin 21 mg/ml IV, contains bacteriostatic water with 1,1 % m/v benzyl alcohol, as preservative.

WHAT HERCEPTIN 21 mg/ml IV IS USED FOR

Herceptin 21 mg/ml IV contains the active substance trastuzumab, which is a humanised monoclonal antibody.

Herceptin 21 mg/ml IV is used for the treatment of breast and gastric cancer if you have high levels of a protein called HER2 and your chemotherapy is finished.

If you have metastatic breast cancer (MBC), Herceptin 21 mg/ml IV is indicated:

- As monotherapy if you have received at least two chemotherapy regimens for your metastatic disease.
- In combination with paclitaxel or docetaxel if you have not received chemotherapy for your metastatic disease.
- in combination with an aromatase inhibitor if you have hormone-receptor positive metastatic breast cancer.

If you have early breast cancer (EBC), Herceptin 21 mg/ml IV is indicated:

- following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable); and
- in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin.
- In combination with adjuvant chemotherapy followed by adjuvant Herceptin 21 mg/ml IV, for locally advanced breast cancer.

If you have metastatic gastric cancer (MGC), Herceptin 21 mg/ml IV is indicated:

- in combination with capecitabine or 5-fluorouracil and cisplatin for metastatic cancer of the stomach or gastro-oesophageal junction if you have not received prior anti-cancer treatment for your metastatic disease.

BEFORE YOU ARE GIVEN HERCEPTIN 21 mg/ml IV

You should not be given Herceptin 21 mg/ml IV:

- If you are allergic to trastuzumab, to murine (mouse) proteins, or to any of the other ingredients of Herceptin 21 mg/ml IV.
- If you have breathing problems at rest or if you need oxygen treatment.
- If you are pregnant or breastfeeding your baby.

Take special care with Herceptin 21 mg/ml IV

- If you have or have had heart failure, coronary artery disease, heart valve disease (heart murmurs) or high blood pressure. This is because Herceptin 21 mg/ml IV can cause heart failure.
- If you have ever had chemotherapy with a medicine called doxorubicin or a medicine related to doxorubicin (your doctor can advise you on this). Herceptin 21 mg/ml IV and doxorubicin-like medicines can damage heart muscle and increase the risk of heart problems when receiving Herceptin 21 mg/ml IV.
- If you are breathless. Herceptin 21 mg/ml IV can cause breathing difficulties. This could be more serious if you are already breathless.
- If you have ever had any other treatment for cancer.

Your doctor will closely supervise your therapy with Herceptin 21 mg/ml IV. Treatment with Herceptin 21 mg/ml IV may affect the heart. Therefore, your heart function will be checked before and during the treatment with Herceptin 21 mg/ml IV. If you develop any signs of heart failure (that is, inadequate pumping of blood by the heart), you may have to stop Herceptin 21 mg/ml IV.

It may take up to 7 months for Herceptin 21 mg/ml IV to be removed from the body. Therefore, you should tell your doctor or pharmacist that you have had Herceptin 21 mg/ml IV if you start any new medicine in the 7 months after stopping treatment.

Use in children and adolescents
Herceptin 21 mg/ml IV is not recommended for anyone under the age of 18 years.

Pregnancy and breastfeeding
You must not use Herceptin 21 mg/ml IV if you are pregnant. Herceptin 21 mg/ml IV can cause harm to the foetus (unborn baby), in some cases death to the foetus, when taken by a pregnant woman.

Before starting treatment, you must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant.

If you are a woman or a man receiving Herceptin 21 mg/ml IV, you are advised to use a highly effective form of contraception, including a barrier method, while receiving Herceptin 21 mg/ml IV and for at least 7 months after your last Herceptin 21 mg/ml IV dose.

Do not breastfeed your baby during Herceptin 21 mg/ml IV therapy and for 7 months after the last dose of Herceptin 21 mg/ml IV.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given Herceptin 21 mg/ml IV.

Driving and using machines
It is not known whether Herceptin 21 mg/ml IV could affect your ability to drive a car or operate machinery. However, if you experience symptoms, such as chills or fever, during an infusion of Herceptin 21 mg/ml IV, you should not drive or use machines until these symptoms disappear.

Taking other medicines with Herceptin 21 mg/ml IV
Please tell your doctor or pharmacist that you have had Herceptin 21 mg/ml IV if you start any medicine in the 6 months after stopping treatment with Herceptin 21 mg/ml IV.
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

HOW TO RECEIVE HERCEPTIN 21 mg/ml IV

Dosage and frequency of administration

Herceptin 21 mg/ml IV is given as an intravenous infusion ("drip") directly into your veins. Your doctor will prescribe a dose and treatment regimen that is right for you. The number of infusions you receive will depend on how you respond to the treatment. Your doctor will discuss this with you.

POSSIBLE SIDE EFFECTS

Herceptin 21 mg/ml IV can cause side effects. Some of these side effects may be serious and may lead to hospitalisation or death.

Not all side effects reported for Herceptin 21 mg/ml IV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Herceptin 21 mg/ml IV, please consult your doctor, pharmacist or healthcare professional for advice.

Herceptin 21 mg/ml IV administration can result in severe hypersensitivity reactions (including anaphylaxis), infusion reactions and pulmonary (lung/respiratory) events. These may cause death. In most cases, these symptoms occurred during or within 24 hours of administration of Herceptin 21 mg/ml IV.

During a Herceptin 21 mg/ml IV infusion, chills, fever and other flu-like symptoms may occur. These are very common. They mainly occur with the first infusion and are temporary. Other infusion-related symptoms are: feeling sick (nausea), vomiting, pain, increased muscle tension and shaking, headache, dizziness, breathing difficulties, wheezing, high or low blood pressure, heart rhythm disturbances (palpitations, heart fluttering or irregular heart beat), swelling of the face and lips, rash and feeling tired. These symptoms can be serious and some patients have died (see "Take special care with Herceptin 21 mg/ml IV").

You should tell your doctor immediately if you notice:

- breathlessness (including breathlessness at night)
- cough
- swelling of the lips, face or throat
- fluid retention (swelling) in the legs or arms or
- palpitations (heart fluttering or irregular heart beat)

Heart problems can occur and are serious. They include weakening of the heart muscle possibly leading to heart problems, and heart rhythm disturbances. Your doctor will monitor your heart regularly during treatment.

Taking Herceptin 21 mg/ml IV can result in serious and potentially deadly lung problems, including:

- A severe shortness of breath
- Too little oxygen in the body
- Weakening of the heart valve between the heart and the lungs
- Swelling of the lungs
- Fluid in or around the lungs
- Scarring of the lungs

Problems like these may occur after an infusion of Herceptin 21 mg/ml IV.

Some effects mainly occur with the first infusion and during the first few hours after the start of the infusion. Occasionally, symptoms start later than six hours after the infusion begins. Sometimes, symptoms may improve and then get worse later. If either of these happens to you, contact your doctor immediately.

Frequent side effects of Herceptin 21 mg/ml IV are:

- swelling of the face and lips
- heart rhythm disturbances
- weakness
- chest pain
- joint pain
- allergic reactions
- abnormal blood counts (anaemia, low platelet count and low white blood count)
- constipation
- heartburn (dyspepsia)
- infections including bladder and skin infections
- shingles
- inflammation of the breast
- inflammation of the pancreas or liver
- kidney disorders
- increased muscle tone /tension (hypertonia)
- tremor
- numbness or tingling of the fingers
- wheezing
- diarrhoea
- skin rashes
- abdominal pain
- muscle pain
- itchiness
- dry mouth and skin
- dry or watery eyes
- sweating
- feeling weak and unwell
- anxiety
- depression
- abnormal thinking
- dizziness
- loss of appetite
- weight loss
- altered taste

and toes

- nail disorders
- hair loss
- inability to sleep (insomnia)
- sleepiness (somnolence)
- nose bleeds
- bruising
- haemorrhoids
- arthritis
- hand-foot syndrome (palms of hands or soles of feet tingle, become numb, painful, swollen or red)
- asthma
- lung disorders
- back pain
- neck pain
- bone pain
- acne
- leg cramps
- blood pressure changes
- anaphylactic reactions
- failure of lungs to develop in the womb
- loss of eyelashes
- abnormal kidney development in the womb

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

STORING AND DISPOSING OF HERCEPTIN 21 mg/ml IV

Store out of reach of children.

Vials must be stored in a refrigerator (2 °C - 8 °C).

Do not use this medicine after the expiry date (EXP) stated on the outer carton and on the vial label.

Disposal of unused/expired medicine:

The release of pharmaceuticals in the environment should be minimised. Medicines should not be disposed of via wastewater and disposal through household waste should be avoided. Use established collection systems, if available in your location.

PRESENTATION OF HERCEPTIN 21 mg/ml IV

Each pack of Herceptin 21 mg/ml IV contains one vial of Herceptin 21 mg/ml IV and one vial of Bacteriostatic water for injection for Herceptin.

IDENTIFICATION OF HERCEPTIN 21 mg/ml IV

Herceptin 21 mg/ml IV is a white to pale yellow lyophilised (“freeze-dried”) powder in a clear, colourless glass vial with a rubber stopper, sealed with an aluminium cap and flip-off disk.

The Bacteriostatic water for injection for Herceptin is a clear, colourless liquid in a clear, colourless glass vial with a rubber stopper, sealed with an aluminium cap and flip-off disk.
The lyophilised powder must be reconstituted and diluted before use, using the Bacteriostatic water for injection for Herceptin.

REGISTRATION NUMBERS

Herceptin 21 mg/ml IV: 34/26/0419

Bacteriostatic Water for Injection for Herceptin: 34/32.4/0420

NAME AND ADDRESS OF REGISTRATION HOLDER

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