

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

HERZUMA 150 mg powder for concentrate for solution for infusion

HERZUMA 440 mg powder for concentrate for solution for infusion

BACTERIOSTATIC WATER FOR INJECTION FOR HERZUMA diluent for injection

Read all of this leaflet carefully before you are given HERZUMA.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- **HERZUMA** 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 is in this leaflet

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

1. What HERZUMA is and what it is used for

HERZUMA contains the active substance trastuzumab, which is a monoclonal antibody. Monoclonal antibodies attach to specific proteins or antigens in the body. **HERZUMA** is designed to bind selectively to an antigen 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 **HERZUMA** binds to HER2 it stops the growth of such cells and causes them to die.

Your doctor may prescribe **HERZUMA** for the treatment of breast and gastric cancer when:

- You have early breast cancer, with high levels of a protein called HER2.

- You have metastatic breast cancer (breast cancer that has spread beyond the original tumour) with high levels of HER2. **HERZUMA** may be prescribed in combination with the chemotherapy medicine paclitaxel or docetaxel as first treatment for metastatic breast cancer or it may be prescribed alone if other treatments have proved unsuccessful. It is also used in combination with medicines called aromatase inhibitors with patients with high levels of HER2 and hormone receptor-positive metastatic breast cancer (cancer that is sensitive to the presence of female sex hormones).
- You have metastatic gastric cancer with high levels of HER2 when it is in combination with the other cancer medicines capecitabine or 5-fluorouracil and cisplatin.

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

HERZUMA should not be administered to you

- If you are hypersensitive (allergic) to trastuzumab or any of the other ingredients of **HERZUMA** (see **Contents of the pack and other information**).
- If you are allergic to murine proteins (proteins that come from mice).
- If you have breathing problems at rest or if you need oxygen treatment.
- If you are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).

Warnings and precautions

Take special care with **HERZUMA**.

Your doctor will closely supervise your therapy.

Heart checks

Treatment with **HERZUMA** alone or with a taxane may affect the heart, especially if you have ever used an anthracycline (taxanes and anthracyclines are two other kinds of medicine used to treat cancer). The effects may be moderate to severe and could cause death. Therefore, your heart function will be checked before, during (every three months) and after (up to two to five years) treatment with **HERZUMA**. If you develop any signs of heart failure (inadequate pumping of blood by the heart), your heart function may be checked more frequently (every six to eight weeks), you may receive treatment for heart failure or you may have to stop **HERZUMA** treatment.

Tell your doctor or health care provider before being given **HERZUMA** if:

- You have had heart failure, coronary artery disease, heart valve disease (heart murmurs), high blood pressure, taken any high blood pressure medicine or are currently taking any high blood pressure medicine.
- You have ever had or are currently using a medicine called doxorubicin or epirubicin (medicines used to treat cancer). These medicines (or any other anthracyclines) can damage heart muscle and increase the risk of heart problems with **HERZUMA**.
- You suffer from breathlessness, especially if you are currently using a taxane. **HERZUMA** can cause breathing difficulties, especially when it is first given. This could be more serious if you are already breathless. Very rarely, patients with severe breathing difficulties before treatment have died when they were given **HERZUMA**.
- You have ever had any other treatment for cancer.

Children and adolescents

HERZUMA is not recommended for children and adolescents under the age of 18 years.

Other medicines and HERZUMA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

It may take up to 7 months for **HERZUMA** to be removed from the body. Therefore, you should tell your healthcare provider that you have had **HERZUMA** if you start any new medicine in the 7 months after stopping treatment.

Pregnancy, breastfeeding and fertility

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given **HERZUMA**.
- You must not use **HERZUMA** if you are pregnant. **HERZUMA** can cause harm to the foetus (unborn baby), in some cases death to the foetus, when taken by a pregnant woman.
- If you are a woman or a man receiving **HERZUMA** you are advised to use a highly effective form

of contraception, including a barrier method, during treatment with **HERZUMA** and for at least 7 months after your treatment has ended.

- Do not breastfeed your baby during **HERZUMA** therapy and for 7 months after the last dose of **HERZUMA** as **HERZUMA** may pass to your baby through your breast milk.

Driving and using machines:

HERZUMA may affect your ability to drive a car or operate machines. However, if during treatment you experience symptoms, such as dizziness, sleepiness, chills or fever, you should not drive or use machines until these symptoms disappear.

HERZUMA (used as preservative in bacteriostatic water for injection) contains Benzyl alcohol
Benzyl alcohol has been linked with the risk of toxicity in young children. Do not give to your newborn baby and children less than 3 years old. Any unused portion after reconstitution must be discarded.

3. How to use HERZUMA

Before starting the treatment, your doctor will determine the amount of HER2 in your tumour. Only patients with a large amount of HER2 will be treated with **HERZUMA**. **HERZUMA** should only be given by a doctor or nurse. Your doctor will prescribe a dose and treatment regimen that is right for you. The dose of **HERZUMA** depends on your body weight.

HERZUMA is given as an intravenous infusion (“drip”) directly into your veins. The first dose of your treatment is given over 90 minutes and you will be observed by a health professional while it is being given in case you have any side effects. If the first dose is well tolerated the next doses may be given over 30 minutes. The number of infusions you receive will depend on how you respond to the treatment. Your doctor will discuss this with you.

For early breast cancer, metastatic breast cancer and metastatic gastric cancer, **HERZUMA** is given every 3 weeks. **HERZUMA** may also be given once a week for metastatic breast cancer.

If you are given too much HERZUMA

As **HERZUMA** is administered by your doctor or nurse, it is unlikely that you will be given too much.

There are no known side effects of receiving

too much **HERZUMA**.

If you forget to use HERZUMA

Since a health care provider will administer **HERZUMA**, it is unlikely that the dose will be missed.

If you stop using HERZUMA

Do not stop using **HERZUMA** without talking to your doctor first. All doses should be taken at the right time every week or every three weeks (depending on your dosing schedule). This helps your medicine work as well as it can.

It may take up to 7 months for **HERZUMA** to be removed from your body. Therefore, your doctor may decide to continue to check your heart functions, even after you finish treatment.

4. Possible side effects

HERZUMA can have side effects.

Not all side effects reported for **HERZUMA** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **HERZUMA**, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- **HERZUMA** administration can result in hypersensitivity reactions, including anaphylaxis, which is a severe, potentially life-threatening allergic reaction.
- Signs of an allergic reaction are swelling of your face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles and feeling tired.

An allergic reaction could happen within the first few hours of your injection or later.

- **HERZUMA** administration can also result in pulmonary (lung/respiratory) events and infusion reactions such as chills, fever other flu-like symptoms. 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 heartbeat) and pulmonary (lung / respiratory) events

These are all very serious side effects which may cause death. You may need urgent medical attention or hospitalisation. In most cases, these symptoms occurred during or within 24 hours of administration of trastuzumab.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- breathlessness (including breathlessness at night)
- cough
- fluid retention (swelling) in the legs or arms
- palpitations (heart fluttering or irregular heartbeat)

These are all serious side effects. You may need urgent medical attention.

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 and after treatment, but you should tell your doctor immediately if you notice any of the above symptoms.

Taking HERZUMA 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.

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. If this happens to you, contact your doctor immediately.

Sometimes, symptoms may improve and then get worse later.

If you experience any of the above symptoms when your treatment with **HERZUMA** has finished, you should see your doctor and tell them that you have previously been treated with **HERZUMA**.

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

Frequent:

- Infections, such as throat, bladder, lungs or skin infections
- Shingles
- Diarrhoea or constipation
- Heartburn (dyspepsia)
- Skin rash, itchy rash
- Chest pain
- Abdominal pain
- Joint pain, muscle pain, leg cramps, increased muscle tone or tension (hypertonia)
- Muscle tightness and muscle stiffness
- Conjunctivitis ('pink eye'), watery eyes
- Nose bleeds, runny nose
- Hair loss and loss of eye lashes
- Tremor
- Hot flushes
- Dizziness
- Nail disorders
- Weight loss, loss of appetite
- Inability to sleep (insomnia), sleepiness (somnolence)
- Altered taste

- Bruising
- Numbness or tingling of the fingers and toes
- Redness, swelling or sores in your mouth and/or throat
- Pain, swelling, redness or tingling of hands and/or feet
- Headache
- Cough
- Nausea (feeling sick), vomiting (being sick)
- Inflammation of the breast, pancreas or liver
- Kidney disorders
- Pain in the arms, legs, back, neck or bones
- Dry mouth, skin or eyes
- Sweating
- Feel weak and unwell
- Anxiety, depression, abnormal thinking
- Asthma or lung disorders
- Acne
- Haemorrhoids (Piles)
- Low blood cell count causing fatigue
- Low platelet count causing increased bruising
- Impaired balance
- Pain or discomfort during urination
- Low levels of white blood cells causing infection and can include fever, rashes, fever and or chills and sweating
- Blood pressure increased causing headache, fatigue and dizziness
- Blood pressure decreased causing dizziness and fainting
- Irregular heart beat, pounding of the heart
- Heart failure
- Heart problems including the heart to become enlarged, thickened, or stiffened, affecting its ability to pump blood effectively.
- Throat pain

- Hiccups
- Nose bleeds
- Running nose
- Lip swelling
- Face swelling
- Painful or difficult urination
- Breast pain
- Chills

Less frequent:

- Deafness
- Bumpy rash
- Blood infection
- Inflammation or scarring of the lungs causing chest discomfort
- Accumulation of fluid in the heart, causing chest pain, fever and fatigue
- Wheezing

Frequency unknown:

- Abnormal or impaired blood clotting
- Swelling or bleeding at the back of the eyes
- Shock (Inability of heart to pump sufficient blood causing shortness of breath, rapid or weak pulse and fainting)
- Swelling of the lining of the heart
- Kidney failure
- Spreading of cancer cells in the body causing pain
- High potassium level in blood causing muscle weakness
- Fluid accumulation in brain
- Loss of eyebrows or eyelashes
- Bleeding in retinas of eyes
- Abnormal rhythm or sound of heart

- Inflammation of the tiny filters in the kidneys which may cause fatigue and or elevated blood pressure
- Low amniotic fluid during pregnancy which may cause abdominal discomfort and or reduced foetal movement
- Underdevelopment of lungs and kidneys
- Inflammation of the protective membranes (meninges) surrounding the brain and spinal cord causing headache and nausea
- Condition caused by rapid death of cancer cells, releasing their contents into the bloodstream causing nausea and vomiting, muscle cramps and fatigue
- Swelling of eyes, lips and or throat
- Disorder of the skin and mucous membranes causing a rash , fever, body aches (Stevens-Johnson syndrome)
- Inflammation of thin membrane around the heart causing chest pain
- Scarring of lung tissue causing fatigue and shortness of breath and or dry cough
- Lung issues causing difficulty breathing, accumulation of fluid in the lung, sudden tightening of muscle around the airways, decreased oxygen in the body, swelling of the larynx (voice box) which lead to shortness of breath, fatigue, coughing

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, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **HERZUMA**.

5. How to store HERZUMA

Before reconstitution

- Store at 2 °C to 8 °C.

After reconstitution

- Chemical and physical in use stability of the reconstituted solution has been demonstrated for 48 hours at 2 °C to 8 °C. From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2 °C to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HERZUMA contains

The active substance is trastuzumab.

HERZUMA 150 mg: Each vial contains 150 mg trastuzumab.

HERZUMA 440 mg: Each vial contains 440 mg trastuzumab.

The other ingredients are α,α -trehalose dihydrate, L-histidine, L-histidine hydrochloride, polysorbate 20.

Sugar free.

BACTERIOSTATIC WATER FOR INJECTION FOR HERZUMA: Each vial contains 20 ml sterile bacteriostatic water for injection with 1,1 % *m/v* benzyl alcohol.

What HERZUMA looks like and contents of the pack

HERZUMA 150 mg: White to yellow powder for solution infusion, which is supplied in a 20 mL type I clear glass vial with a grey chlorobutyl rubber stopper and an aluminium flip-off seal with an orange polypropylene flip-off cap, packed in an outer carton.

HERZUMA 440 mg: White to yellow powder for solution infusion, which is supplied in a 50 mL type I clear glass vial with a grey chlorobutyl rubber stopper and an aluminium flip-off seal with a blue polypropylene flip-off cap, packed in an outer carton.

BACTERIOSTATIC WATER FOR INJECTION FOR HERZUMA: Clear, colourless solution, free of visible particles in a 20 mL type I clear glass vial closed with a grey chlorobutyl rubber stopper and aluminium flip-off seal with a white polypropylene flip-off cap, packed in an outer carton.

Holder of Certificate of Registration

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Customer Care: 0860 ADCOCK / 232625

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