PATIENT INFORMATION LEAFLET FOR

TRASTUZUMAB CIPLA

SCHEDULING STATUS: S4

TRASTUZUMAB CIPLA 440 mg, Concentrate for Solution for Infusion

Trastuzumab

Bacteriostatic Water for Injection for TRASTUZUMAB CIPLA, Diluent.

Contains sugar: Sorbitol 337, 9 mg

Read all of this leaflet carefully before you start taking this medicine

Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor, pharmacist or other healthcare provider.
- TRASTUZUMAB CIPLA 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 TARSTUZUMAB CIPLA is and what it is used for
2. What you need to know before you receive TRASTUZUMAB CIPLA
3. How to receive TRASTUZUMAB CIPLA
4. Possible side effects
5. How to store TRASTUZUMAB CIPLA

6. Contents of the pack and other information.

1. What TRASTUZUMAB CIPLA is and what it is used for

TRASTUZUMAB CIPLA (trastuzumab) belongs to a class of medicine known as humanised monoclonal antibodies.

TRASTUZUMAB CIPLA 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), TRASTUZUMAB CIPLA is indicated:

- As single medicine therapy (monotherapy) if you have received at least two chemotherapy regiments 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), TRASTUZUMAB CIPLA is indicated:

- Following surgery, chemotherapy (whether the therapy is administered before the primary cancer treatment, or therapy is administered after the primary treatment) and radiotherapy (if applicable); and
- In combination with chemotherapy given before cancer treatment consisting of docetaxel and carboplatin.

If you have Metastatic gastric cancer (MGC), TRASTUZUMAB CIPLA 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.

2. What you need to know before you receive TRASTUZUMAB CIPLA

TRASTUZUMAB CIPLA should not be administered to you

- If you are hypersensitive to trastuzumab, to murine (mouse) proteins, or to any of the other ingredients of TRASTUZUMAB CIPLA (**listed in section 6**).
- If you have problems breathing when you are resting or if you need to use oxygen.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Tell your doctor or healthcare professional before being given the injection if:

Take special care with TRASTUZUMAB CIPLA

- If you have or have had heart failure (serious heart problems), disease of your coronary artery, heart valve disease (heart murmurs) or high blood pressure. This is because TRASTUZUMAB CIPLA 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). TRASTUZUMAB CIPLA and doxorubicin-like medicines can damage heart muscle and increase the risk of heart problems when receiving TRASTUZUMAB CIPLA.

Use in children and adolescents:

TRASTUZUMAB CIPLA is not recommended for anyone under the age of 18 years.

Other medicines and TRASTUZUMAB CIPLA

Please tell your doctor or pharmacist that you have had TRASTUZUMAB CIPLA if you start any medication in the 7 months after stopping treatment with TRASTUZUMAB

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

It may take up to 7 months for TRASTUZUMAB CIPLA to be removed from the body. Therefore, you should tell your doctor, pharmacist or nurse that you have had TRASTUZUMAB CIPLA if you start any new medicine in the 7 months after stopping treatment.

TRASTUZUMAB CIPLA with food, drink and alcohol

TRASTUZUMAB CIPLA can cause diarrhoea. For this reason, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken.

Avoid raw fruits, vegetables, whole grain breads, cereals and seeds.

Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea.

Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina.

Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Pregnancy, breastfeeding and fertility

You must not use if you are pregnant. TRASTUZUMAB CIPLA 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 TRASTUZUMAB CIPLA, you are advised to use a highly effective form of contraception, including a barrier method, while receiving TRASTUZUMAB CIPLA and for at least 7 months after your last TRASTUZUMAB CIPLA dose. Do not breastfeed

your baby during TRASTUZUMAB CIPLA therapy and for 7 months after the last dose of TRASTUZUMAB CIPLA. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given TRASTUZUMAB CIPLA.

Medical or laboratory supervised pregnancy test should be done before treatment with TRASTUZUMAB CIPLA.

Male patients receiving TRASTUZUMAB CIPLA should also be advised to use a highly effective form of contraception, including a barrier method, while receiving TRASTUZUMAB CIPLA and for at least 7 months after your last TRASTUZUMAB CIPLA dose

Consider sperm conservation in males before treatment with TRASTUZUMAB CIPLA.

Driving and using machines:

If you feel sleepy or experience chills or fever, during an infusion of TRASTUZUMAB CIPLA, you should not drive or use machines until you know how the treatment affects you.

Important information about some of the ingredients of TRASTUZUMAB CIPLA

Bacteriostatic Water for Injection for TRASTUZUMAB CIPLA contains benzyl alcohol as a preservative. If you are allergic to benzyl alcohol, the TRASTUZUMAB CIPLA should be reconstituted with water for injection. Any unused portion must be discarded.

TRASTUZUMAB CIPLA contains sorbitol

TRASUZUMAB CIPLA contains sorbitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take TRASTUZUMAB CIPLA.

3. How to receive TRASTUZUMAB CIPLA

Do not share medicines prescribed for you with any other person.

Always receive TRASTUZUMAB CIPLA exactly as your doctor or pharmacist has told you.

You should check with your doctor or pharmacist if you are not sure.

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 TRASTUZUMAB CIPLA.

TRASTUZUMAB CIPLA 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 TRASTUZUMAB CIPLA depends on your body weight.

TRASTUZUMAB CIPLA 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 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 might administer TRASTUZUMAB CIPLA along with other chemotherapy paclitaxel or docetaxel. Your doctor will discuss this with you.

If you missed a dose of TRASTUZUMAB CIPLA

If you missed a dose of TRASTUZUMAB CIPLA by one week

or less, then the usual maintenance dose of TRASTUZUMAB CIPLA will be given as soon as possible. If you missed a dose of TRASTUZUMAB CIPLA by more than one

week, a re-loading dose of TRASTUZUMAB CIPLA will be given. Your doctor will make a decision based on your current health and situation

If you stop receiving TRASTUZUMAB CIPLA

Do not stop using this medicine 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 TRASTUZUMAB CIPLA to be removed from your body. Therefor your doctor may decide to continue to check your heart functions, even after you finish treatment. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or healthcare professional.

4. Possible side effects

TRASTUZUMAB CIPLA can have side effects.

Not all side effects reported for TRASTUZUMAB CIPLA are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Some of these side effects caused by TRASTUZUMAB CIPLA may be serious and may lead to hospitalisation or death. TRASTUZUMAB CIPLA 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 TRASTUZUMAB CIPLA. During a TRASTUZUMAB CIPLA infusion, chills, fever and other flu-like symptoms may occur. These are very frequent. 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.

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 heartbeat).

Heart problems can occur and are serious. They include weakening of the heart muscle possibly leading to heart problems such as heart failure, and heart rhythm disturbances. Your doctor will monitor your heart regularly during treatment. Frequent side effects of TRASTUZUMAB CIPLA are: swelling of the face and lips, wheezing, heart rhythm disturbances, diarrhoea, weakness, skin rashes, chest pain, abdominal pain, joint pain, muscle pain, allergic reactions, itchiness, abnormal blood counts (anaemia, low platelet count and low white blood count), dry mouth and skin, constipation, dry or watery eyes, heartburn (dyspepsia), sweating, infections including bladder and skin infections, feeling weak and unwell, shingles, anxiety, inflammation of the breast, depression, inflammation of the pancreas or liver, abnormal thinking, kidney disorders, dizziness, increased muscle tone /tension (hypertonia), loss of appetite, tremor, weight loss, numbness or tingling of the fingers and toes, altered taste, nail disorders, asthma, hair loss, lung disorders, inability to sleep (insomnia), back pain, sleepiness (somnolence), neck pain, nose bleeds, bone pain, bruising, acne, haemorrhoids, leg cramps, arthritis, blood

pressure changes, hand-foot syndrome (palms of hands or soles of feet tingle, become numb, painful, swollen or red).

Taking TRASTUZUMAB CIPLA 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 (inflammation of lung tissue)
- Fluid in or around the lungs
- Scarring of the lungs (fibrotic tissue changes in the lungs)

Problems like these may occur after an infusion of TRASTUZUMAB CIPLA. 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. Not all side effects reported for TRASTUZUMAB CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRASTUZUMAB CIPLA, consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA **website**, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By re**porting**

side effects, you can help provide more information on the safety of TRASTUZUMAB CIPLA.

5. How to store TRASTUZUMAB CIPLA

Vials with lyophilized powder must be stored in a refrigerator at 2 ºC to 8 °C.

Keep the vials in the outer carton until required for use.

The reconstituted solution can be stored in a refrigerator at 2 °C to 8 °C for 28 days.

Do not freeze the reconstituted solution.

The reconstituted solution contains a preservative and is therefore suitable for multiple use.

Solution for infusion: Solutions of TRASTUZUMAB CIPLA for infusion

are stable in polyvinylchloride or polyethylene bags containing are 0,9 % sodium chloride at 2 °C to 8 °C for 24 hours. The product is not intended to be stored after dilution, unless the dilution has taken place under controlled and validated aseptic conditions.

Do not use this medicine after the expiry date 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.

STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN

6. Contents of the pack and other information

The active substance is Trastuzumab 440 mg.

BACTERIOSTATIC WATER FOR INJECTION FOR TRASTUZUMAB CIPLA: This solvent for the reconstitution of contains bacteriostatic water with 1,1 % v/v benzyl alcohol which is the preservative.

The other ingredients are D-sorbitol, hydrochloride monohydrate, L-histidine polyethylene glycol and water for injection

What TRASTUZUMAB CIPLA looks like and contents of the pack

TRASTUZUMAB CIPLA is an off white to pale yellow colour intact or largely intact cake.

Bacteriostatic Water for Injection for TRASTUZUMAB CIPLA is a clear colourless solution, free from visible particles.

The reconstituted solution is colourless to pale yellow, free from visible particles.

TRASTUZUMAB CIPLA is packed in a clear colourless 50 mL glass vial, with grey bromobutyl rubber stopper, and covered with a lavender colour flip-off seal. The vial is packed in an outer carton.

Bacteriostatic Water for Injection for TRASTUZUMAB CIPLA:

is packed in a clear colourless 20 mL glass vial, with grey bromobutyl rubber stopper, and covered with a red colour flip-off seal. The vial is packed in an outer carton.

Holder of certificate of registration

Cipla Medpro (Pty) Ltd.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

Registration number(s)

TRASTUZUMAB CIPLA: 53/26/0051

Bacteriostatic Water for Injection for TRASTUZUMAB CIPLA:

53/26/0051

This leaflet was last revised in

First authorisation: **07 April 2020**

Latest renewal: **Not applicable**

Revision: **26 August 2026**

Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.