PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

OGIVRI 150 mg

Lyophilised powder for concentrate for solution for infusion

Trastuzumab

Contains sugar: sorbitol

Read all of this leaflet carefully before you start receiving OGIVRI

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- OGIVRI 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 OGIVRI is and what it is used for

OGIVRI contains the active substance trastuzumab, which is a monoclonal antibody. Monoclonal antibodies attach to specific proteins or antigens. Trastuzumab 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 OGIVRI binds to HER2 it stops the growth of such cells and causes them to die.

If you have metastatic breast cancer (MBC), OGIVRI 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), OGIVRI 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 OGIVRI, for locally advanced breast cancer.

If you have metastatic gastric cancer (MGC), OGIVRI 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 give OGIVRI

You should not be administered OGIVRI if:

- you are allergic (hypersensitive) to trastuzumab, to murine (mouse) proteins or any of the other ingredients of OGIVRI (listed in section 6).
- you have severe breathing problems at rest due to your cancer or if you need oxygen treatment.
- you are pregnant or breastfeeding as safety has not been proven.

Warnings and precautions

Special care should be taken with OGIVRI

Heart checks

Treatment with OGIVRI 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 OGIVRI. 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 OGIVRI treatment.

Tell your doctor or healthcare professional before being given the injection 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 OGIVRI.
- you suffer from breathlessness, especially if you are currently using a taxane. OGIVRI 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 OGIVRI.
- you have ever had any other treatment for cancer.

Other medicines and OGIVRI

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 OGIVRI to be removed from the body. Therefore you should tell your healthcare professional that you have had OGIVRI if you start any new medicine in the 7 months after stopping treatment.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking OGIVRI.

Pregnancy

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

- You should use effective contraception during treatment with OGIVRI and for at least 7 months after treatment has ended.
- Your doctor will advise you of the risks and benefits of taking OGIVRI during pregnancy. In rare cases, a reduction in the amount of (amniotic) fluid that surrounds the developing baby within the womb has been observed in pregnant women receiving OGIVRI. This condition may be harmful to your baby in the womb and has been associated with the lungs not developing fully resulting in foetal death.

Breast-feeding

Do not breast-feed your baby during OGIVRI therapy and for 7 months after the last dose of OGIVRI as this medicine may pass to your baby through your breast milk.

Driving and using machines

It is not known whether OGIVRI can affect your ability to drive a car or operate machines. However, if during treatment you experience symptoms, such as chills or fever, you should not drive or use machines until these symptoms disappear.

OGIVRI contains sorbitol

OGIVRI 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 OGIVRI.

3. How to receive OGIVRI

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

Your doctor will prescribe a dose and treatment regimen that is right for you. The dose of OGIVRI depends on your body weight. OGIVRI is given as an infusion into a vein (intravenous infusion).

Each vial of OGIVRI 150 is reconstituted with 7,2 ml of sterile water for injection (not supplied). This yields a solution for single-dose use, containing approximately 21 mg/ml trastuzumab at a pH of approximately 6.0.

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 and metastatic breast cancer, OGIVRI is given every 3 weeks. OGIVRI may also be given once a week for metastatic breast cancer.

If you receive more OGIVRI 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 forget to take or give OGIVRI

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

Effects when treatment with OGIVRI is stopped

It may take up to 7 months for OGIVRI 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

OGIVRI can have side effects.

Not all side effects reported for OGIVRI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking

OGIVRI, please consult your doctor, pharmacist or other healthcare professional for advice.

During a OGIVRI infusion, chills, fever and other flu like symptoms may frequently occur. Other infusion-related symptoms are: feeling sick (nausea), vomiting, pain, increased muscle tension and shaking, headache, dizziness, rash, weakness, high or low blood pressure, breathing difficulties, wheezing, fast heart beat. Some of these symptoms can be serious and some patients have died.

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

- swelling of the hands, feet, ankles, face, lips mouth or throat which may cause difficulty in swallowing or breathing,
- rash or itching

These are very serious side effects. If you have them, you may have had a serious allergic reaction to OGIVRI. You may need urgent medical attention or hospitalisation.

Heart problems can occur frequently during treatment with OGIVRI and less frequently after treatment. Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following**:**

- difficulty breathing, especially when lying down,
- cough,
- fluid retention (swelling) in the legs or arms,
- palpitations (heart fluttering or irregular heart beat).

These are all serious side effects. You may need urgent medical attention. If you experience any of the above symptoms when your treatment with OGIVRI has

finished, you should see your doctor and tell them that you have previously been treated with OGIVRI

Frequent side effects of OGIVRI:

- infections
- diarrhoea
- constipation
- heartburn (dyspepsia)
- weakness
- skin rashes
- chest pain
- abdominal pain
- joint pain
- low counts of red blood cells and white blood cells (which help fight infection) sometimes with fever
- muscle pain
- conjunctivitis (inflammation of the eye)
- watery eyes
- nose bleeds
- runny nose
- hair loss
- tremor
- hot flush
- dizziness
- nail disorders
- weight loss

- loss of appetite
- inability to sleep (insomnia)
- altered taste
- low platelet count
- 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
- breathlessness
- headache
- cough
- vomiting
- nausea
- allergic reactions
- throat infections
- bladder and skin infections
- shingles
- inflammation of the breast
- inflammation of the pancreas or liver
- kidney disorders
- increased muscle tone or tension (hypertonia)
- pain in the arms and/or legs
- itchy rash
- sleepiness (somnolence)
- haemorrhoids
- itchiness
- dry mouth and skin

- dry eyes
- sweating
- feeling weak and unwell
- anxiety
- depression
- abnormal thinking
- asthma
- infection of lungs
- lung disorders
- back pain
- neck pain
- bone pain
- acne
- leg cramps
- bronchitis
- loss of feeling in a part of your body
- feeling off balance
- chest discomfort
- swelling in the arms or legs
- high blood pressure
- throat pain
- inflammation of the throat
- hiccups
- shortness of breath during exercise
- inflammation of the lining of the stomach
- problems with your liver
- formation of ridges on your fingernails

- pain affecting muscles and bones
- pain or difficulty passing water
- breast pain
- inflammation of the tissue inside your body
- changes to the nail structure

Less frequent side effects of OGIVRI:

- deafness
- bumpy rash
- blood infection
- weakness
- jaundice
- inflammation or scarring of the lungs

Other side effects that have been reported with OGIVRI use: frequency cannot be estimated from the available data

- abnormal or impaired blood clotting
- anaphylactic reactions
- high potassium levels
- swelling of the brain
- swelling or bleeding at the back of the eyes
- shock
- swelling of the lining of the heart
- slow heart rate
- abnormal heart rhythm
- respiratory distress
- respiratory failure

- acute accumulation of fluid in the lungs
- acute narrowing of the airways
- abnormally low oxygen levels in the blood
- difficulty in breathing when lying flat
- liver damage/failure
- swelling of the face, lips and throat
- kidney failure
- abnormally low levels of fluid around baby in womb
- failure of lungs to develop in the womb
- abnormal kidney development in the womb

Some of the side-effects you experience may be due to your underlying cancer. If you receive **OGIVRI** in combination with chemotherapy, some of them may also be due to the chemotherapy.

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 pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications: https://sahpra.org.za/wpcontent/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf or to Imperial Market Access Healthcare South Africa (Pty) Ltd. via email: pvimperiallogistics@dpworld.com

By reporting side effects, you can help provide more information on the safety of OGIVRI.

5. How to store OGIVRI

Store all medicines out of reach of children.

- Vials with lyophilised powder: Store vials at 2–8 °C. Protect from light.
- Reconstituted solution OGIVRI 150:
- After reconstitution with sterile water for injection, the reconstituted solution is physically and chemically stable for 48 hours at 2–8 °C. Any remaining reconstituted solution should be discarded. Do not freeze the reconstituted solution. Protect from light.
- Solutions of OGIVRI 150 are physically and chemically stable in infusion bags/systems of PVC, PE or PP containing sodium chloride 0,9 % solution for injection when stored at or below 30 °C for 24 hours. Protect from light.
- From a microbiological point of view, the OGIVRI 150 reconstituted solution and infusion should be used immediately.
- Do not use after the expiry date stated on the label / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OGIVRI contains

The active substance is trastuzumab.

Each single use vial contains 150 mg of trastuzumab.

Reconstituted OGIVRI concentrate contains 21 mg/ml trastuzumab.

Contains sugar: sorbitol 115,2 mg per vial.

The other ingredients are: D-Sorbitol, L-histidine, L-histidine hydrochloride monohydrate, polyethylene glycol 3350.

What OGIVRI looks like and contents of the pack

OGIVRI 150 is an off white to pale yellow, lyophilised powder.

Reconstituted product: colourless to pale yellow solution.

Contents of the pack:

OGIVRI 150: Carton containing 1 vial of OGIVRI 150 in a clear 15 ml type 1 glass vial, closed with a grey chlorobutyl rubber stopper coated with fluororesin laminate and sealed with a lavender flip-off seal.

Holder of Certificate of Registration

Imperial Market Access South Africa (Pty) Ltd.

Gateway Industrial Park

57 Sarel Baard Crescent

Centurion

South Africa

0157

This leaflet was last revised in

09 September 2024

Registration numbers

OGRIVI 150: 52/26/0215.213

Access to the corresponding Professional Information

https://pi-pil-repository.sahpra.org.za/