OGIVRI

contains the active ingredient trastuzumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OGIVRI. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given OGIVRI against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist..

Keep this leaflet with the medicine.
You may need to read it again.

What OGIVRI is used for

OGIVRI contains an active ingredient called trastuzumab.

OGIVRI belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents. There are many different classes of antineoplastic agents. OGIVRI belongs to a class called monoclonal antibodies

Monoclonal antibodies are proteins made in a laboratory. These proteins are designed to recognise and bind to other unique proteins in the body.

OGIVRI binds selectively to a protein called human epidermal growth factor receptor 2 (HER2).

HER2 is found in large amounts on the surface of some cancer cells.

When OGIVRI binds to HER2 it stops the growth and spread of the cancer cells.

OGIVRI is used to treat breast and gastric cancer. It is only used in patients whose tumor has tested positive to HER2.

OGIVRI may be used alone or with other medicines that treat breast cancer, such as an aromatase inhibitor (hormone receptor positive breast cancer) or a taxane (e.g. paclitaxel or docetaxel).

For the treatment of gastric cancer OGIVRI is used with chemotherapy medicines cisplatin and capecitabine (or 5FU).

For further information about the other medicines you are receiving with OGIVRI, please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) leaflet.

Ask your doctor if you have any questions why OGIVRI has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you are given OGIVRI

When you must not take it

Do not take OGIVRI if you have an allergy to:

- **OGIVRI**
- **any ingredient listed at the end of this leaflet or**
- **any protein of Chinese hamster origin**

Some symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; rash, itching or hives on the skin or swelling of the face, lips, tongue or other parts of the body.

- **you have breast cancer that has not spread (non-metastatic) and**
- **you have had an LVEF test result (which measures how well your heart can pump blood) of less than 45% or**
- **you have symptoms of heart failure**
  Symptoms of heart failure may include
  - shortness of breath or tire easily after light physical activity (such as walking)
  - shortness of breath at night, especially when lying flat
  - swelling of the hands or feet due to fluid build up
  - abnormal or irregular heartbeat

If you are not sure if you should start receiving OGIVRI, talk to your doctor.

Tell your doctor if:

- **you have a history of heart disease with:**
  - angina (chest pain)
  - cardiac arrhythmias (abnormal beating of the heart)
  - heart failure (where the heart cannot pump blood normally)
  - coronary artery disease (also known as CAD, a condition where plaque builds up inside the arteries)
  - poorly controlled high blood pressure
- **you have previously been treated with chemotherapy medicines known as anthracyclines (e.g. doxorubicin); these medicines can damage heart muscle and increase the risk of heart problems with OGIVRI**
  Your doctor will monitor your heart function closely before and during your treatment with OGIVRI. Your heart function may also be monitored for years after ceasing OGIVRI treatment.
- **if you have any breathing or lung problems**
- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**
  Allergic or anaphylactic reactions can occur with OGIVRI treatment (known as infusion or administration related reactions).
  Your doctor or nurse will monitor you for side effects during treatment. See "side effects" for symptoms to look out for.
- You have a hereditary fructose intolerance (HFI)
- You have other deficiencies in sorbitol metabolism
- **you are pregnant or intend to become pregnant**
  OGIVRI may be harmful to an unborn baby. If there is a need for OGIVRI treatment when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
  You should use effective contraception to avoid becoming pregnant while you are being treated with OGIVRI and for 7 months after stopping treatment.
- **you are breast-feeding or plan to breast-feed**
  It is not known if OGIVRI passes into breast milk. It is recommended that you discontinue breast-feeding while you are being treated with OGIVRI and not restart breast-feeding until 7 months after completing OGIVRI treatment.

If you have not told your doctor about any of the above, tell them before you are given OGIVRI.

Use in children

The safety and effectiveness of OGIVRI in children under 18 years of age have not been established.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

OGIVRI treatment with gemcitabine, vinorelbine, a taxane or radiation therapy can increase the chance of lung problems (interstitial lung disease).

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving OGIVRI.

Tell your doctor or pharmacist that you have had OGIVRI if you start any new medication in the seven months after stopping treatment.
It may take up to seven months for OGIVRI to be removed from your body.

How to take OGIVRI

Follow all directions given to you by your doctor or nurse carefully.
They may differ from the information contained in this leaflet.

OGIVRI must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

OGIVRI is given by "drip" into a vein (intravenous (IV) infusion).

The first OGIVRI infusion is given over 90 minutes. If the first infusion is well tolerated, your drip time may be shortened to 30 minutes.

For the treatment of breast cancer, OGIVRI is given either once a week or once every three weeks. It may be given alone or in combination with other medicines used to treat breast cancer.

For the treatment of gastric cancer OGIVRI is given every three weeks in combination with other medicines used to treat gastric cancer.

Your doctor will decide how long you should receive OGIVRI, this will depend on your response to the medicine and the state of your disease.

If you forget to take it

As OGIVRI is given under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive OGIVRI, make another appointment as soon as possible.

Your doctor will decide when and how much your next dose of OGIVRI will be.

If you take too much (overdose)

As OGIVRI is given to you under the supervision of your doctor it is unlikely that you will be given too much. However, if you experience any side effects after being given OGIVRI, tell your doctor immediately.

While you are using OGIVRI

Things you must do

Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reaction

Some signs and symptoms include;

- swelling of your face, lips, tongue or throat with difficulty breathing,
- swelling of other parts of your body
- shortness of breath, wheezing or trouble breathing
- rash, itching or hives on the skin
- feeling sick (nausea)
- fever, chills
- feeling tired
- headache

Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems.

Some signs and symptoms of heart problems are

- shortness of breath or getting
- tired easily after light physical activity (such as walking)
- shortness of breath at night, especially when lying flat
- swelling of the hands or feet due to fluid build up
- cough
- abnormal or irregular heartbeat

Please follow all your doctors' instructions if any of these symptoms require medication.

Tell all doctors, dentists and pharmacists who are treating you that you are receiving OGIVRI.

Tell your doctor if you become pregnant or intend to start a family while receiving OGIVRI.

Be sure to keep all of your appointments with your doctor so that your progress can be checked
Your doctor may perform regular tests.

Things you must not do

Do not stop your OGIVRI treatment without talking to your doctor first.

Tell your doctor if you feel that OGIVRI is not helping your condition.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how OGIVRI affects you.
If you experienced symptoms during your treatment with OGIVRI you should not drive or operate machinery.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are receiving OGIVRI.

OGIVRI helps most people with HER2 positive breast and gastric cancer but it may have some unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Because OGIVRI may be used with other medicines that treat breast and gastric cancer, it may be difficult for your doctor to tell whether the side effects are due to OGIVRI or due to the other medicines.

For further information about the side effects of any other medicines you are receiving, please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) leaflets for these medicines.

During an infusion

Tell your doctor or nurse immediately if you notice any of the following while receiving an infusion (particularly during the first infusion):

- swelling of your face, lips, tongue or throat with difficulty breathing
- swelling of other parts of your body such as your hands or feet
- shortness of breath, wheezing or trouble breathing
- abnormal or irregular heartbeat
- rash, itching or hives on the skin
- feeling sick (nausea) or vomiting, diarrhoea
- pain or discomfort (including
- stomach pain, back pain, chest or neck pain)
- fever or chills
- headache
- fatigue or tiredness
- cough

These may be serious side effects.

You may require urgent medical attention.

Your doctor may prescribe medication to stop the side effects from occurring.

After an infusion

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- swelling of your face, lips, tongue or throat with difficulty breathing
- severe shortness of breath, wheezing or trouble breathing
- severe chest pain spreading out to the arms, neck, shoulder and/or back
- rash, itching or hives on the skin
- fever or chills
- abnormal or irregular beating of the heart
- severe swelling of the hands, feet or legs
- severe coughing

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

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

- any of the side effects listed above
- getting tired more easily after light physical activity, such as walking
- shortness of breath, especially when lying down or being woken from your sleep with shortness of breath
- runny or blocked nose, or nosebleeds
- insomnia (difficulty sleeping)
- confusion
- weakness, soreness in muscles and/or joints
- increased cough
- feeling dizzy, tired, looking pale
- flu and/or cold like symptoms, frequent infections such as fever, severe chills, sore throat or mouth ulcers
- hot flushes
- diarrhoea
- changes in weight (gain or loss)
- redness, dryness or peeling of the hands or feet (hand-foot syndrome)
- pain in hands or feet
- unusual hair loss or thinning
- nail problems
- eye problems such as producing more tears, swollen runny eyes or conjunctivitis (discharge with itching of the eyes and crusty eyelids)

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

After using OGIVRI

Storage

OGIVRI will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.

Availability

OGIVRI is available in two presentations;

- Powder for intravenous infusion (drip into the vein). Supplied as a single dose vial, available in 150 mg strength.
- Powder for intravenous infusion (drip into the vein). Supplied as a Pharmacy Bulk Pack in 440 mg vial with bacteriostatic water for injection

It is important to check the product labels to ensure that the correct presentation is being given as prescribed

Product description

What OGIVRI looks like

OGIVRI is a white to pale yellow powder which is dissolved before use.

After dissolving, the OGIVRI solution should appear as a clear colourless to yellow solution.

Ingredients

Each vial of OGIVRI contains 150 mg or 440 mg of the active ingredient trastuzumab.

It also contains;

- L-histidine hydrochloride monohydrate
- L-histidine
- Sorbitol
- Macrogol 3350
- Hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

The trastuzumab protein is made using Chinese hamster ovary cells.

Manufacturer/Distributor/ Supplier

OGIVRI is made/distributed/supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

OGIVRI powder for intravenous infusion:

150 mg: AUST R 288222

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