

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using OGIVRI?

OGIVRI contains the active ingredient trastuzumab (rch). OGIVRI is used to treat breast and gastric cancer.

For more information, see Section [1. Why am I receiving OGIVRI?](#) in the full CMI.

### 2. What should I know before I use OGIVRI?

Do not use if you have ever had an allergic reaction to trastuzumab (rch) or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given OGIVRI?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with OGIVRI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use OGIVRI?

- OGIVRI is given by “drip” into a vein (intravenous (IV) infusion).
- OGIVRI must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

More instructions can be found in Section [4. How will I be given OGIVRI?](#) in the full CMI.

### 5. What should I know while using OGIVRI?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using OGIVRI.</li><li>• Tell your doctor or nurse immediately if you have any signs and symptoms of an allergic or anaphylactic reaction</li><li>• Tell your doctor or nurse immediately if you have any signs and symptoms of heart problems</li><li>• Tell your doctor if you become pregnant or intend to start a family while receiving OGIVRI.</li><li>• Tell your doctor if you feel that OGIVRI is not helping your condition.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop your OGIVRI treatment without talking to your doctor first.</li><li>• Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how OGIVRI affects you.</li><li>• If you experienced symptoms during your treatment with OGIVRI you should not drive or operate machinery.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• OGIVRI will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature</li><li>• between 2°C and 8°C.</li></ul>

For more information, see Section [5. What should I know while being treated with OGIVRI?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include fever or chills, headache, cough, fatigue or tiredness. Serious side effects include swelling of your face, lips, tongue or throat with difficulty breathing, rash, itching or hives of the skin, irregular heartbeat.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# OGIVRI

**Active ingredient:** *trastuzumab (rch)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using OGIVRI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OGIVRI.**

**Where to find information in this leaflet:**

- [1. Why am I receiving OGIVRI?](#)
- [2. What should I know before I am given OGIVRI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given OGIVRI?](#)
- [5. What should I know while being treated with OGIVRI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I receiving OGIVRI?

**OGIVRI contains the active ingredient trastuzumab (rch).** 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 tumour 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.**

## 2. What should I know before I am given OGIVRI?

### Warnings

**Do not use OGIVRI if:**

- you have had an allergic reaction to:**
  - trastuzumab (rch)
  - any of the ingredients 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

Always check the ingredients to make sure you can use this medicine.

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

**Check with 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
- 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.

- **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 are pregnant or intend to be pregnant.**
- **you are breast-feeding or plan to breast-feed**
- you have hereditary fructose intolerance (HFI).
- you have other deficiencies in sorbitol metabolism.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

**Check with your doctor if 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.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

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 breastfeeding until 7 months after completing OGIVRI treatment.

## Use in children

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

## 3. What if I am taking other medicines?

**Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

## 4. How will I be given OGIVRI?

### How much OGIVRI will be given

- 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.

### When you will be given OGIVRI

- 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 miss a dose of OGIVRI

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 use too much OGIVRI

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

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while being treated with OGIVRI?

### Things you should do

#### Call your doctor straight away 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
- have any signs and symptoms of heart problems. 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.
- If you become pregnant or if you intend to start a family while receiving OGIVRI.

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.

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

### Things you should not do

- Do not stop using this medicine suddenly without talking to your doctor first.
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how OGIVRI affects you.

OGIVRI may cause dizziness in some people

- 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.

### Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

#### Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Serious side effects

Serious side effects	What to do
<b>During an infusion</b> <ul style="list-style-type: none"><li>• swelling of your face, lips, tongue or throat with difficulty breathing</li><li>• swelling of other parts of your body such as your hands or feet</li><li>• shortness of breath, wheezing or trouble breathing</li><li>• abnormal or irregular heartbeat</li><li>• rash, itching or hives on the skin</li><li>• feeling sick (nausea) or vomiting, diarrhoea</li><li>• pain or discomfort (including stomach pain, back pain, chest or neck pain)</li><li>• fever or chills</li><li>• headache</li></ul>	<b>Tell your doctor or nurse immediately if you notice any of these serious side effects while receiving an infusion (particularly during the first infusion).</b> <p>These may be serious side effects.</p> <p>You may require urgent medical attention.</p> <p>Your doctor may prescribe</p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>fatigue or tiredness</li> <li>cough</li> </ul>	medication to stop the side effects from occurring.
<b>After an infusion:</b> <ul style="list-style-type: none"> <li>swelling of your face, lips, tongue or throat with difficulty breathing</li> <li>severe shortness of breath, wheezing or trouble breathing</li> <li>severe chest pain spreading out to the arms, neck, shoulder and/or back</li> <li>rash, itching or hives on the skin</li> <li>fever or chills</li> <li>abnormal or irregular beating of the heart</li> <li>severe swelling of the hands, feet or legs</li> <li>severe coughing</li> </ul>	<b>Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these serious side effects.</b>  These are serious side effects. You may need urgent medical attention.

### Less serious side effects

Less serious side effects side effects	What to do
<ul style="list-style-type: none"> <li>getting tired more easily after light physical activity, such as walking</li> <li>shortness of breath, especially when lying down or being woken from your sleep with shortness of breath</li> <li>runny or blocked nose, or nosebleeds</li> <li>insomnia (difficulty sleeping)</li> <li>weakness, soreness in muscles and/or joints</li> <li>increased cough</li> <li>feeling dizzy, tired, looking pale</li> <li>flu and/or cold like symptoms, frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>hot flushes</li> <li>diarrhoea</li> <li>changes in weight (gain or loss)</li> <li>redness, dryness or peeling of the hands or feet (hand-foot syndrome)</li> <li>pain in hands or feet</li> <li>unusual hair loss or thinning</li> <li>nail problems</li> <li>eye problems such as producing more tears, swollen runny eyes or conjunctivitis</li> </ul>	<b>Tell your doctor or nurse as soon as possible if you notice any of these side effects.</b>

(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.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What OGIVRI contains

<b>Active ingredient (main ingredient)</b>	Each vial of OGIVRI contains 150 mg or 440 mg of the active ingredient trastuzumab.  The trastuzumab protein is made using Chinese hamster ovary cells.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>L-histidine hydrochloride monohydrate</li> <li>L-histidine</li> <li>Sorbitol</li> <li>Macrogol 3350</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### 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.

OGIVRI powder for intravenous infusion:

150 mg: AUST R 288222

440 mg: AUST R 288223

### Who distributes OGIVRI

Maxx Pharma Pty Ltd

Level 20, 181 William St,  
Melbourne Victoria 3000  
Phone: 1800 202 981  
Email: [medical@maxxpharma.com.au](mailto:medical@maxxpharma.com.au)

This leaflet was prepared in October 2024.