



# UNLOCK Herzuma

(Trastuzumab biosimilar)

**What you need to know**

※ Herzuma (trastuzumab biosimilar) is a prescription only medicine. Herzuma powder for intravenous infusion is available as

- Herzuma 150 mg vial containing 150 mg of trastuzumab
- Herzuma 440 mg vial containing 440 mg of trastuzumab

※ This booklet should only be given to patients receiving Herzuma.

※ Discuss your treatment plan with your healthcare professional. Use Herzuma strictly as directed.

 **Herzuma**<sup>®</sup>  
Trastuzumab



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**Herzuma** is a biosimilar medicine to the reference biological medicine Herceptin. If you have never heard of biosimilars before, you may have questions about it. This brochure may answer some of your queries, to help you feel more confident about your treatment.

Herzuma has risks and benefits. Always discuss your condition and treatment plan with your healthcare professional and ask your doctor if Herzuma is right for you. This brochure is not intended to replace any professional advice given by your healthcare provider. If you have any questions, please seek the advice of your healthcare provider.

## What is a biosimilar?



A biosimilar is a biological medicinal product that is highly similar to an already licensed biological medicinal product (reference product).<sup>1-3</sup> In the case of trastuzumab, the reference product is Herceptin.

A biologic is a medicinal product that is derived from living organisms including humans, animals or microorganisms, and is used in treating many life-threatening and chronic diseases.<sup>1,4</sup>

Small differences occur because biological medicinal products are large, highly complex molecules derived from living organisms. These differences are similar to the differences that can occur between batches of a reference biological product.<sup>5</sup>

Despite these small differences, biosimilar medicines are expected to be as safe and effective as the reference biological product.<sup>5</sup>

## How are biosimilars regulated and approved?



Biosimilars are approved according to the same standards of **quality, safety, and efficacy** set up by regulatory agencies such as the European Medicines Agency (EMA) and Medsafe that apply to all biologic medicines.

Biosimilars must demonstrate a **positive-benefit risk balance** by showing biosimilarity to the reference medicinal product, achieved by all scientific evidence generated in extensive comparability studies assessing quality, non-clinical, and clinical aspects.<sup>6</sup>

## Are biosimilars used globally?



Since 2006, biosimilars have been used extensively all over the world. In New Zealand, Pharmac has funded biosimilar medicines starting from 2012. Since then, local and global clinical experience has demonstrated that biosimilar medicines are safe and effective.<sup>5</sup>

## Benefits of using biosimilars



Biosimilars are bringing about changes to the healthcare landscape, emerging as a cost-saving alternative to highly priced reference biologics.<sup>7,8</sup>

The introduction of biosimilars has led to

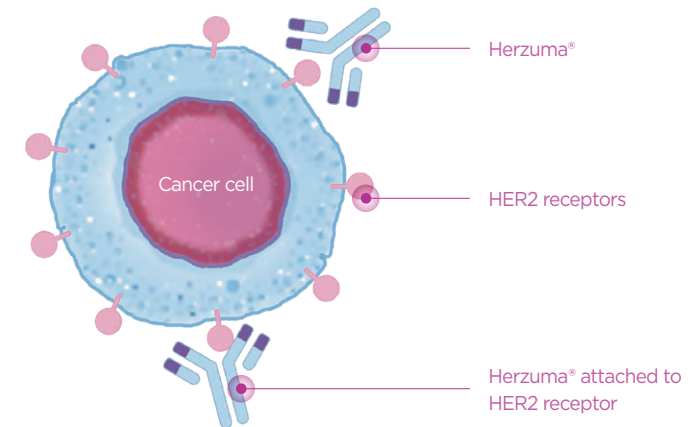
1. **Significant reduction in treatment costs** for health services as they lower costs while offering highly similar efficacy and safety to that of the originator.<sup>8,13,14</sup>
2. **Increase in patient access** to essential biological therapeutic products.<sup>8,13,14</sup>

Furthermore, biosimilars are expected to reduce the pressure on healthcare budgets, and increase access to the promising new combination regimens, biologics, or other expensive drugs.<sup>7,8</sup>

## Herzuma and how it works



HERZUMA is a biosimilar of Herceptin. The active substance in Herzuma, trastuzumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to the HER2 protein on the surface of target cells. By attaching to HER2, trastuzumab activates cells of the immune system, which then kill the tumour cells. Trastuzumab also stops HER2 producing signals that cause the tumour cells to grow.<sup>9</sup>



## What is Herzuma used to treat?<sup>10</sup>



Herzuma is used to treat adult patients with HER2-positive:

- Early breast cancer
- Metastatic breast cancer
- Metastatic gastric cancer

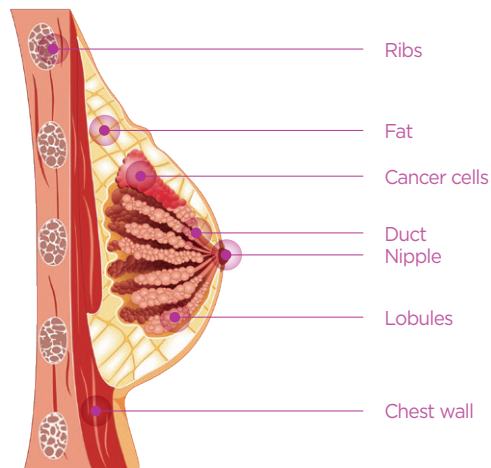
※ If you experience any side effects or experience any discomfort during your treatment period, please speak to your doctor, pharmacist or healthcare professional.

## What is breast cancer?



Breast cancer is the most common cancer for New Zealand women and the third most common cancer overall in New Zealand. It affects one in nine New Zealand women over their lifetime.<sup>11</sup>

In healthy breast tissue, cells divide in a controlled manner to create new cells. Breast cancer arises when the cells in your breast start to rapidly divide in an uncontrolled way, and eventually form a lump of cells, called tumour.<sup>15</sup>



### Causes<sup>12,15</sup>

The reasons why a person may develop breast cancer are not completely understood. However, the likelihood of a woman developing breast cancer is increased by certain risk factors such as age, family history, breast density, female hormone exposure, radiation exposure or lifestyle factors. Having one or more of these factors doesn't mean that you will definitely get breast cancer. Many people who have these factors may never get the disease, while some without any risk factors may still develop it.

### Types<sup>27</sup>

When describing the type of breast cancer, some of the factors that are considered are how much the cancer has grown and whether it has spread to other parts of the body. Typically, breast cancer can be categorised as non-invasive or invasive.

## HER2 - positive early breast cancer



Early breast cancer means that the cancer has spread within the breast or to the local lymph glands (i.e., lymph nodes under the arm), but not to other parts of the body.<sup>16</sup>

HER2 (human epidermal growth factor receptor 2) is a protein involved in normal cell growth. Some breast cancers have large amounts of HER2 on their surface (so-called, HER2 protein overexpression). They are called HER2-positive breast cancers.

About 20% of the 3300 Kiwis diagnosed with breast cancer each year will have HER2-positive breast cancer.<sup>17</sup>

### How is HER2-positive early breast cancer diagnosed?<sup>18</sup>

If you are diagnosed with breast cancer, doctors will take a tissue sample from the breast (biopsy) and perform a test to see if the cancer is HER2-positive. HER2-positive status is diagnosed using laboratory tests, which will help determine which treatment is best for you. Treatment will depend on whether your breast cancer is in the early stages or is more advanced.

### How is HER2-positive early breast cancer treated?<sup>9,12,19</sup>

The main treatments for breast cancer include: surgery, radiotherapy, chemotherapy, hormone therapy and targeted therapy.

You might also have a combination of these treatments, depending on your situation. Your doctor will take many different factors into account when deciding which treatment is best for you.

Therapies such as Herizuma® specifically target HER2-positive breast cancer and help improve patient outcomes. This drug works by blocking the effects of HER2 and encouraging the immune system (the body's natural defence) to attack and kill cancer cells with HER2 overexpression.

## HER2 - positive metastatic breast cancer



HER2 (human epidermal growth factor receptor 2) is a protein involved in normal cell growth. Some breast cancers have large amounts of HER2 on their surface (so-called, HER2 protein overexpression). They are called HER2-positive breast cancers. About 20% of the 3300 Kiwis diagnosed with breast cancer each year will have HER2-positive breast cancer.<sup>17</sup>

It's possible for breast cancer to spread to other parts of the body, usually through the blood or the axillary lymph nodes – small lymphatic glands which would filter bacteria or cells from the mammary gland. If that happens, the disease is known as secondary, or metastatic cancer.<sup>16,18,27</sup>

### How is HER2-positive metastatic breast cancer diagnosed?

If you are diagnosed with breast cancer, doctors will take a tissue sample from the breast (biopsy) and perform a test to see if the cancer is HER2-positive. HER2-positive status is diagnosed using laboratory tests, which will help determine which treatment is best for you. Advanced or metastatic breast cancer (also known as stage IV breast cancer), means that the disease has spread to other parts of the body (metastasised). Breast cancer may spread to anywhere in the body, but most commonly goes to the liver, lungs, lymph nodes, brain and bones.<sup>16,18</sup>

### How is HER2-positive metastatic breast cancer treated?<sup>9,28</sup>

HER2-positive metastatic breast cancer may sometimes be treated with surgery. However, this is not common practice as it is unlikely to remove all the cancer cells, particularly if the cancer has spread to more than one location. More typically, patients with metastatic breast cancer will receive systemic therapy consisting of endocrine therapy, chemotherapy, and/or biological agents depending on the individual's treatment plan. Biological therapies, such as Herceptin®, which target HER2-positive breast cancer, have been developed to work with chemotherapy to help improve patient outcomes.

These drugs work by blocking the effects of HER2 activation and encouraging the immune system (the body's natural defence) to attack and kill the cancer cells.

## What is gastric cancer?<sup>20-21</sup>



Stomach cancer, also known as gastric cancer, is when abnormal cells in the stomach start to grow and divide in an uncontrolled way.

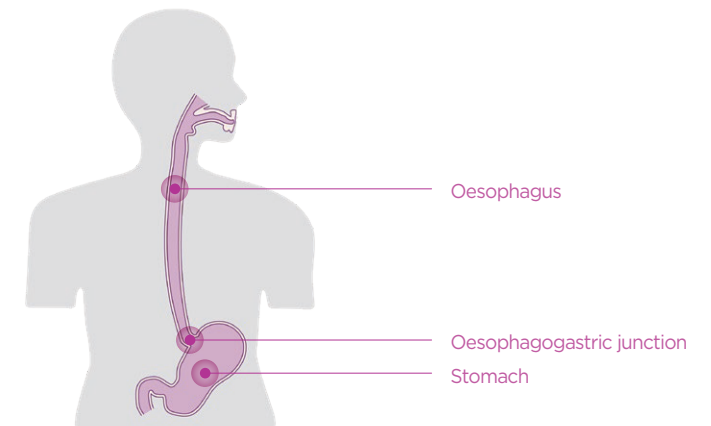
The stomach is part of the digestive system. It's in the upper left side of the tummy (abdomen). The top of the stomach is joined to the food pipe (also known as oesophagus) and the other end is joined to the bowel.

Cancer can start in any part of the stomach and any layer of the stomach wall. Your treatment depends on where in the stomach the cancer starts.

Most stomach cancers start in the glandular cells of the stomach lining. These are called adenocarcinomas.

There are also other less common types of stomach cancer. Some of those are:

- Non-Hodgkin lymphoma: cancer of lymphatic system
- Gastrointestinal stromal tumours (GIST): rare type of soft tissue sarcoma found in the digestive system
- Neuroendocrine tumours (NETs): they start in the neuroendocrine cells of the stomach and are also called carcinoid tumours



### Causes<sup>22-23</sup>

The reasons why stomach cancer may develop are not completely understood. However, there are certain known risk factors for gastric cancer, including (but not limited to):

- Gastric infection with *Helicobacter pylori*
- Age and gender, with higher prevalence in older males
- Smoking tobacco
- Family history of gastric cancer

## HER2 - positive metastatic gastric cancer



HER2 (human epidermal growth factor receptor 2) is a protein found on the surface of cells and involved in normal cell growth and repair. High levels of HER2 are found in some types of breast, oesophageal and stomach cancer, and help the cancer cells grow and survive. These are known as HER2-positive cancers. About 1 in 5 breast and stomach cancers are HER2-positive.<sup>24</sup>

**Metastatic gastric cancer** indicates that cancer cells from the primary tumour (where the cancer first formed) have travelled through the blood or lymph system and have formed new tumours (metastatic tumours) in other parts of the body. While the tumours may be in different locations, they are still considered the same type of cancer as the primary tumour.<sup>25</sup>

### How is HER2-positive metastatic gastric cancer diagnosed?<sup>29</sup>

If you are diagnosed with gastric cancer, doctors will take a tissue sample from the tumour (a biopsy) and test to see if it is HER2-positive. HER2-positive status is diagnosed using laboratory tests, which will help determine which treatment is best for you. Treatment will depend on whether your cancer is in its early stages or is more advanced. Before the start of the treatment, your blood tests will be taken and the heart scan will be performed.

### How is HER2-positive metastatic gastric cancer treated?<sup>9,10,26</sup>

The main treatments for gastric cancer are surgery and chemotherapy. Other treatments may include: radiotherapy, targeted therapy and immunotherapy.

The treatment you are going to receive will depend on:

- the type and size of the stomach cancer you have
- the location of the tumour
- if your tumour has spread
- your general health

HER2-positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction can be treated with Herzuma in combination with other cancer medicines.

Herzuma binds to the HER2 protein and prevents signals that promote cancer cell growth and division.

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This medicine is subject to additional monitoring to allow quick identification of new safety information. You can help by reporting any side effects you may get at the following contact channels.



# UNLOCK Herzuma

(Trastuzumab biosimilar)

## What you need to know

Herzuma is a fully funded medicine for patients with HER2 positive early breast cancer, HER2 positive metastatic breast cancer and HER2 positive advanced gastric or gastro-oesophageal junction cancer - restrictions apply.

Additional Data Sheets and Consumer Medicine Information can be obtained from the Medsafe website at <https://www.medsafe.govt.nz/medicines/infosearch.asp>



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