



Vegzelma™

GUIDE FOR PATIENTS

“We Walk Together. Now and Always”

- ※ Vegzelma (bevacizumab biosimilar) is a prescription only medicine. Vegzelma concentrate for solution for infusion is available as:
 - Vegzelma 100mg single dose vials containing 4mL of bevacizumab (25mg/mL)
 - Vegzelma 400mg single dose vials containing 16mL of bevacizumab (25mg/mL)
- ※ This booklet should only be given to patients receiving Vegzelma.
- ※ Discuss your treatment plan with your healthcare professional. Use Vegzelma strictly as directed.

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Vegzelma is a biosimilar medicine to the reference biological medicine Avastin. 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.

Vegzelma has risks and benefits. Always discuss your condition and treatment plan with your healthcare professional and ask your doctor if Vegzelma 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). In the case of bevacizumab, the reference product is Avastin.

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.¹

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.²

Despite these small differences, biosimilar medicines are expected to be as safe and effective as the reference biological product.²

How are biosimilars regulated and approved?

Biosimilars are approved according to the same standards of **quality, safety, and efficacy** set up by regulatory agencies 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.

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.²

Benefits of using biosimilars

Biosimilars are bringing about changes to the healthcare landscape, emerging as a cost-saving alternative to highly priced reference biologics.^{3,4}

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.⁴⁻⁶
- 2. Increase in patient access** to essential biological therapeutic products.⁴⁻⁶

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.^{3,4}

Vegzelma and how it works

VEGZELMA is a biosimilar of Avastin. The active substance in Vegzelma, bevacizumab, is a monoclonal antibody (a type of protein) that selectively binds to and neutralises vascular endothelial growth factor (VEGF). Tumours produce high levels of VEGF, a protein that stimulates blood vessels to grow, thereby providing the tumour with nutrients and oxygen. When Vegzelma blocks the binding of VEGF to its receptors, it neutralises the biologic activity of VEGF and reduces new blood vessels from growing in the tumour. This disrupts the blood supply to the tumour, inhibiting its growth.⁷

What is Vegzelma used to treat?⁸

Vegzelma is registered for the treatment of:

- Metastatic colorectal cancer
- Advanced and/or metastatic renal cell cancer
- Advanced, metastatic or recurrent non-squamous non-small cell lung cancer
- Metastatic breast cancer
- Relapsed high grade malignant glioma
- Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer
- Cervical cancer

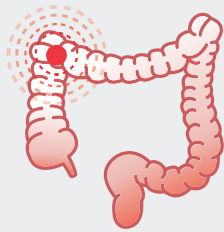
※ If you experience any side effects or experience any discomfort during your treatment period, please speak to your doctor, pharmacist or healthcare professional.

Guide for Patients

What is Vegzelma™

Vegzelma™ is a biosimilar to AVASTIN (bevacizumab).

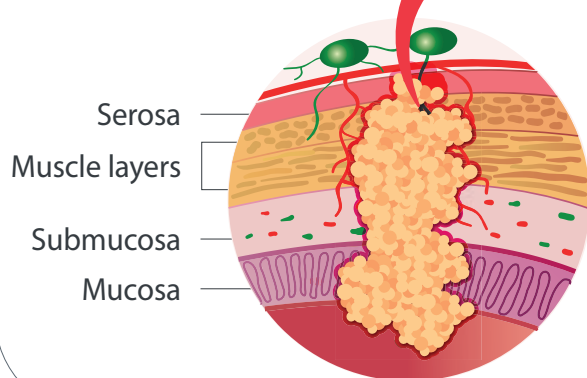
Vegzelma™ Vegzelma is used in combination with chemotherapy to treat patients with metastatic colorectal cancer.⁸



What is metastatic colorectal cancer (mCRC)?

Colorectal cancer develops in the large intestine. If cancer involves distant organs, such as the liver and lungs, it is called metastatic colorectal cancer (mCRC), or stage 4 colorectal cancer.⁹

Spread to other parts of the body¹⁰



Treatment of mCRC

The treatment not only aims to remove the tumour by surgery, but also to target the tumour cells systemically with chemotherapy, or with a combination of chemotherapy and biological targeted therapy.⁹

What is Vegzelma™

Vegzelma™ is a biosimilar to AVASTIN (bevacizumab).

Vegzelma™ Vegzelma is used in combination with chemotherapy to treat patients with unresectable advanced, recurrent or metastatic non-squamous non-small cell lung cancer.⁸



What is non-squamous non-small cell lung cancer (NSCLC)?

Lung carcinomas originate from cells that line the airways (bronchus, bronchioli, and alveoli) of the lungs. Lung carcinomas are divided into two groups (SCLC and NSCLC) based on the appearance of the cells.¹¹

Types of NSCLC

- ✓ **Adenocarcinoma**
that is the most common lung cancer and forms from cells that line the alveoli and make mucous.
- ✓ **Squamous cell carcinoma**
that forms from cells that line the bronchi.
- ✓ **Large cell carcinoma**
that forms from any of the large cells that are throughout the airways.

Treatment of NSCLC

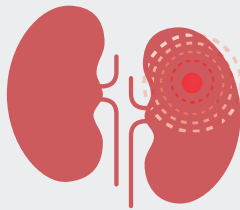
For stage IV NSCLC, cytotoxic combination chemotherapy is the first-line therapy, which might be influenced by cell appearance, age, other medical conditions, and performance status.¹²

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What is Vegzelma™

Vegzelma™ is a biosimilar to AVASTIN (bevacizumab).

Vegzelma™ Vegzelma is used in combination with interferon alfa to treat patients with metastatic renal cell carcinoma (mRCC).⁸



What is metastatic renal cell carcinoma (mRCC)?

When cancer begins in the kidney, it is referred to as renal cell cancer. It can also be called kidney and renal pelvis cancer.¹³ Metastatic RCC (mRCC) is a kidney cancer that has spread to a distant site.¹⁴

Treatment of mRCC¹⁵

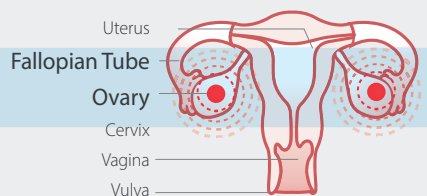
For patients with mRCC, there are 2 pillars of therapy.

- **VEGF-TKIs** that attenuate progression by inhibiting angiogenesis (the process of forming new blood vessels)
- **Immunotherapy** agents that use the body's immune system to recognize and destroy cancer cells

What is Vegzelma™

Vegzelma™ is a biosimilar to AVASTIN (bevacizumab).

Vegzelma™ Vegzelma is used in combination with chemotherapy to treat patients with advanced ovarian cancer.⁸



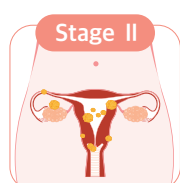
What is ovarian cancer (OC)?

Ovarian cancer is a group of diseases that originates in the ovaries, or in the related areas of the fallopian tubes and the peritoneum (a membrane lining that surround and protect abdominal organs).¹⁶

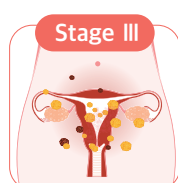
Classification of OC

FIGO staging¹⁷

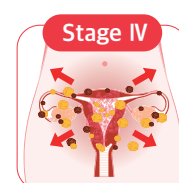
cancer



Cancer is in one or both ovaries and has not spread outside the pelvis or to any lymph nodes



Cancer is in one or both ovaries and has spread outside the pelvis to tissues in the belly



Cancer has spread to other parts of the body, such as the liver, lungs, or brain

Treatment of OC

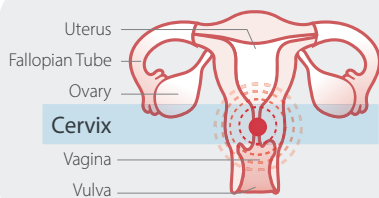
Treatment for ovarian cancer usually involves a combination surgery and chemotherapy.¹⁶ Surgery is the recommended first treatment for ovarian cancer whenever possible.¹⁷ If surgery first is not an option, chemotherapy is given first to try to shrink the cancer before surgery.¹⁷

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What is Vegzelma™

Vegzelma™ is a biosimilar to AVASTIN (bevacizumab).

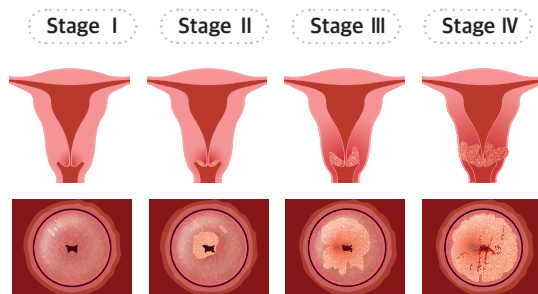
Vegzelma™ Vegzelma is used in combination with chemotherapy to treat patients with persistent, recurrent or metastatic cervical cancer.⁸



What is cervical cancer?

Cervical cancer is a common cancer of the cervix in the female reproductive system that starts as areas of abnormal, microscopic cells on the surface of the cervix.¹⁸

Classification of CC



FIGO staging¹⁹

- Stage I** Carcinoma is strictly confined to the cervix
- Stage II** Beyond uterus but not to pelvic wall or lower 1/3 of vagina
- Stage III** Carcinoma extends to the pelvic wall and/or involves lower third of vagina
- Stage IV** Invades mucosa of bladder or rectum, and/or extends beyond true pelvis

Treatment of CC

Cervical cancer treatment are determined based on several factors, including the stage of the cancer, whether the cancer has metastasized to other parts of the body, the size of the tumor, and the patient's age and overall health.¹⁹

Treatment guidelines, recently updated by the NCCN, include surgery, radiation, and chemotherapy alone or in combination, delineated as fertility sparing or nonfertility sparing.¹⁹

What is Vegzelma™

Vegzelma™ is a biosimilar to AVASTIN (bevacizumab).

Vegzelma™ Vegzelma is used to treat patients with brain tumours.⁸



What is glioblastoma (GBM)?

Glioblastoma (GBM), or astrocytoma WHO grade IV, is the most aggressive and fatal primary brain cancer in humans.²⁰ Most glioblastomas manifest rapidly without any prior signs of a lower-grade tumor.²⁰

Symptoms of GBM²¹

- › Headaches
- › Seizures
- › Confusion
- › Memory loss
- › Personality changes
- › Focal neurologic deficits (impairments of nerve, spinal cord, or brain function)

Treatment of recurrent GBM

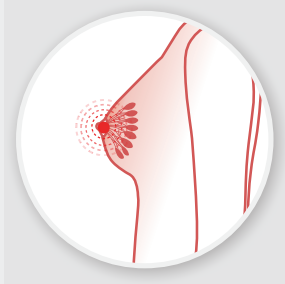
For patients with a recurrent GBM, standards of care are less well defined. Nitrosourea regimens, temozolomide rechallenge, and bevacizumab are some drug therapy options.²²

Guide for Patients

What is Vegzelma™

Vegzelma™ is a biosimilar to AVASTIN (bevacizumab).

Vegzelma™ Vegzelma is used in combination with chemotherapy to treat patients with metastatic breast cancer.⁸



What is metastatic breast cancer (mBC)?

Breast cancer is a disease in which malignant cells form in the tissues of the breast.²³ Metastatic breast cancer — also called stage IV — is breast cancer that has spread to another part of the body, most commonly the bones, lungs, brain, or liver.²⁴

Symptoms of mBC²⁴

Symptoms can be very different depending on the cancer's location, but may include:

- › Back, bone, or joint pain that does not go away
- › Shortness of breath or difficulty breathing
- › Vision problems
- › Difficulty urinating
- › Numbness or weakness anywhere in your body
- › Abdominal bloating, pain, or tenderness
- › Seizures

Treatment of mBC

Patients with metastatic breast cancer usually receive systemic therapy consisting of endocrine therapy, chemotherapy, and/or biological agents depending on the individual's treatment plan.²⁵

How is Vegzelma administered?

Administer as an intravenous infusion.



First infusion

Administer infusion over 90 minutes.



Subsequent infusions

Administer second infusion over 60 minutes, if first infusion is tolerated.



Administer all subsequent infusions over 30 minutes, if second infusion over 60 minutes is tolerated.

*Vegzelma must only be administered by healthcare professionals.

What are the side effects?⁷

All medicines can have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of you being treated with VEGZELMA against the benefits they expect it will have for you.⁷

Some of the most serious side effects are:

- Gastrointestinal perforations (hole in the wall of the stomach, large bowel, or small intestine)
- Bleeding
- Arterial and venous thromboembolism (blood clots in the arteries or veins)

Most frequently observed side effects were:

- High blood pressure (headaches, dizziness, blurred vision)
- Tiredness or weakness
- Diarrhoea
- Abdominal pain

You may not experience any of these side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Vegzelma. Your healthcare team are the best people to guide you on how to manage any side effects.

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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.



Phone: 0800 838 899
Email: medinfo-nz@celltrionhc.com



GUIDE FOR PATIENTS

From 1 March 2025, Vegzelma will be funded under special authority criteria for:

- recurrent respiratory papillomatosis
- ocular conditions
- unresectable hepatocellular carcinoma (liver cancer)
- advanced ovarian cancer.

By 1 August 2025, all people with recurrent respiratory papillomatosis will need to have transitioned to the Vegzelma brand of bevacizumab.

For people with ocular conditions, 'any brand' of bevacizumab will continue to be funded in Health New Zealand | Te Whatu Ora hospitals.

Note: Normal doctor's charges apply.

For more information, visit <https://www.vegzelma.co.nz/>

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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www.celltrionhealthcare.com

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