

# New Zealand Consumer Medicine Information

## VEGZELMA

**Bevacizumab**

**100 mg in 4 mL and 400 mg in 16 mL (25mg/mL) concentrate for solution for infusion**

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### What is in this leaflet

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This leaflet answers some common questions about VEGZELMA infusion.

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 taking VEGZELMA against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What VEGZELMA is used for

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VEGZELMA contains the active ingredient bevacizumab.

VEGZELMA is a biosimilar medicine to AVASTIN®.

VEGZELMA is used to treat brain tumours.

VEGZELMA is used in combination with chemotherapy agents to treat metastatic (spreading) cancer of the large bowel (i.e. in the colon or rectum), breast or cervix.

VEGZELMA is also used for the treatment of lung cancer and cancer of the ovaries and fallopian tubes (which can extend to the lining of surrounding organs such as stomach, liver), in combination with chemotherapy agents.

For the treatment of kidney cancer (renal cell cancer) VEGZELMA is used in combination with interferon therapy (ROFERON A®).

VEGZELMA belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents. There are many different classes of anti-neoplastic agents. VEGZELMA belongs to a class known as anti-angiogenic agents.

Anti-angiogenic agents inhibit angiogenesis (the process of forming new blood vessels in your body).

VEGZELMA selectively binds to vascular endothelial growth factor (VEGF), a protein found on the cells that line blood vessels. Tumours produce high levels of VEGF, which stimulates blood vessels to grow, thereby providing the tumour with nutrients and oxygen.

When VEGZELMA blocks VEGF it disrupts the blood supply to the tumour, stopping or slowing down its growth.

There are many different types of medicines used to treat brain tumours and metastatic cancer of the large bowel, breast, cervix, lung, ovaries/fallopian tubes and kidney.

Your doctor, however, may have prescribed VEGZELMA for another purpose.

**Ask your doctor if you have any questions about why VEGZELMA has been prescribed for you.**

VEGZELMA is not a cure for cancer. VEGZELMA is not addictive.

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

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## **Before you are given VEGZELMA**

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### ***When you must not be given it***

**Do not use VEGZELMA if:**

- 1. you have had an allergic reaction to VEGZELMA or any ingredients listed at the end of this leaflet**  
Symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body or rash, itching or hives on the skin
- 2. you have had an allergic reaction to any proteins that are of Chinese hamster origin or to other recombinant human or humanised antibodies**
- 3. you have lung cancer and have been coughing or spitting up blood**
- 4. the package is torn or shows signs of tampering**
- 5. the expiry date printed on the pack has passed**  
If you take this medicine after the expiry date has passed, it may not work as well.

**If you are not sure if you should be given VEGZELMA, talk to your doctor. Do not give VEGZELMA to children or adolescents.**

Safety and effectiveness in children and adolescents have not been established.

### ***Before you are given it***

**Tell your doctor if:**

- 1. You are pregnant or plan to become pregnant**  
Do not use VEGZELMA if you are pregnant. VEGZELMA may be harmful to your unborn baby.  
  
You should use contraception during treatment with VEGZELMA and for at least 6 months after your last dose. If you become pregnant while you are being treated with VEGZELMA, immediately inform your doctor.  
  
Your doctor will advise you about the use of contraception during your treatment.
- 2. You plan to start a family in the future**  
VEGZELMA may interfere with your ability to become pregnant. Your doctor will advise you of your options prior to starting treatment.
- 3. You are breast-feeding or plan to breast-feed**  
You should not breast-feed while being treated with VEGZELMA and for at least 6 months after your last dose of VEGZELMA. VEGZELMA may interfere with the growth and development of your baby.
- 4. You have any other health problems, especially the following:**
  - inflammation of the bowel (symptoms may include fever, vomiting, diarrhoea and stomach pain) or stomach ulcers
  - hypertension (high blood pressure) - it is important to follow all your doctor's instructions to control your blood pressure
  - history of blood clots or stroke, or you are taking medicine to prevent blood clots (e.g. warfarin)
  - you or anyone in your family suffer from bleeding problems
  - you have had any bleeding in your lungs or have been coughing or spitting up blood

- heart disease
  - low white blood cell counts (neutropenia)
  - you have/had a fistula (a fistula is a permanent abnormal passageway between two organs in the body or between an organ and the exterior of the body).
  - history of diabetes
- 5. You have had major surgery within the last 28 days or have a wound that has not healed properly**
- VEGZELMA can cause an increased risk of post-operative bleeding or problems with wound healing.
- 6. You have had a blocked lung artery (pulmonary embolism)**
- VEGZELMA may increase the risk of recurrence
- 7. If you have had heart disease, received anthracyclines (e.g. Adriamycin® (doxorubicin) a type of chemotherapy used to treat some cancers), or have had radiotherapy to your chest**
- VEGZELMA can increase the risk of developing heart failure.
- 8. You are 65 years of age or older**
- VEGZELMA can increase the risk of blood clots, which can lead to strokes or heart attacks in patients older than 65 years of age compared with younger patients.
- 9. You are allergic to any other medicines, foods, dyes or preservatives**
- If you have not told your doctor about any of the above, tell them before you start taking VEGZELMA.**

### ***Taking other medicines***

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

**Tell your doctor if you have recently received, or are receiving, radiotherapy.**

Some medicines may interfere with VEGZELMA. These include:

- sunitinib malate, a medicine used for the treatment of renal cell carcinoma (RCC) and imatinib-resistant gastrointestinal stromal tumor (GIST)

Some medicines may be affected by VEGZELMA, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking VEGZELMA.

**Ask your doctor or pharmacist if you are not sure about this list of medicines.**

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## **How VEGZELMA is given**

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**Follow all directions given to you by your doctor or pharmacist.**

They may differ from the information contained in this leaflet.

### ***How it is given***

VEGZELMA is prepared by a healthcare professional.

VEGZELMA is given by infusion into a vein (intravenous infusion) by a healthcare professional.

The first infusion is usually given over 90 minutes. If it is well tolerated the second infusion may be given over 60 minutes. Later infusions may be given over 30 minutes.

### ***How much is given***

Your dose depends on your body weight and the type of cancer to be treated. VEGZELMA can be given either once every 2 weeks or once every 3 weeks. Your doctor will prescribe a dose of VEGZELMA that is right for you.

**If you have been given too much VEGZELMA you may develop a severe migraine. If this happens tell your health care professional immediately.**

### ***How long it is given***

The number of infusions you will receive depends on how you are responding to treatment. Your doctor will discuss this with you.

### ***If you miss a dose***

Your doctor will decide when you should be given your next dose of VEGZELMA.

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## **While you are being treated with VEGZELMA**

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### ***Things you must do***

**Tell all doctors, dentists and pharmacists who are treating you that you are being treated with VEGZELMA.**

**Tell your doctor immediately if you become pregnant during treatment with VEGZELMA, or plan to start a family in the near future.**

**Tell your doctor immediately if you are breast-feeding or plan to breast-feed while being treated with VEGZELMA.**

**Tell your doctor if you are planning to have surgery or you have a wound that is not healing properly.**

Tell your doctor if you feel VEGZELMA is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

### ***Things you must not do***

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

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how VEGZELMA affects you.**

VEGZELMA has not been shown to impair your ability to drive or operate machinery.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with VEGZELMA.**

VEGZELMA helps most people with brain tumours and cancer of the large bowel (i.e. colon or rectum), breast, cervix, lung, kidney, and ovarian/fallopian tube (which can extend to the lining of surrounding organs such as stomach, liver) but it may have unwanted side effects in some people.

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.

Because VEGZELMA is used with other medicines that treat cancer (including chemotherapy), it may be difficult for your doctor to tell whether the side effects are due to VEGZELMA or due to the other medicines.

VEGZELMA may exacerbate some chemotherapy side effects when used in combination with chemotherapy agents, including hair loss, nail disorders, pain, redness and/or swelling of your hands and/or soles of your feet, and a feeling of numbness or tingling in the hands or feet.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Tell your doctor if you notice any of the following and they worry you:**

- high blood pressure (symptoms may include headache, dizziness, ringing in the ears, tiredness, blurred vision)
- body pain and/or numbness (unable to sense pain or hot/cold temperatures on your body, arms and legs)
- lack of energy, unusual tiredness or weakness
- diarrhoea; constipation or rectal bleeding (blood in the stools)
- sore mouth, mouth ulcers
- loss of appetite, constantly being thirsty
- shortness of breath
- nose bleed; runny or blocked nose
- dry skin; flaking, swelling or redness of the skin or change in skin colour
- change and/or loss in sense of taste
- blurred vision or other problems with the eyes (including increased production of tears, double vision, a drooping eyelid, shimmering lights in your vision, sensitivity to light or temporary loss of sight)
- dizziness; trouble with your balance, headache; migraines
- frequent infections with symptoms such as fever, severe chills or sore throat
- bleeding or bruising more easily than normal
- changes in your voice or hoarseness
- difficulty speaking or swallowing
- loss of body weight
- abdominal, pelvic, rectal or back pain

These are the more common side effects of VEGZELMA. Mostly these are mild.

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

- severe body pain including headaches
- stomach cramps or pains
- severe diarrhoea, nausea and vomiting
- loss of control of your bladder or bowels; passage of wind or bowel motions through the vagina
- coughing or spitting blood
- pain, redness, swelling and warmth over a vein which may suggest deep vein thrombosis (blood clots in the veins of legs)
- pain and/or swelling in the lower legs, feet or hands

- severe bleeding or problems with your wounds healing after surgery
- seizures (fits), confusion
- sleepiness, drowsiness or fainting
- abscesses (pus-filled sores)
- severe infection with high fever, chills, headache, confusion and rapid breathing
- feeling of numbness or tingling in hands or feet
- dry mouth in combination with thirst and/or reduced or darkened urine
- problems with the heart with breathing difficulties
- increase in heart rate (pulse)
- shortness of breath
- symptoms of an allergic reaction which may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body or rash, itching or hives on the skin

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

Tell your doctor or dentist if you experience pain in the mouth, teeth and/or jaw, swelling or sores inside the mouth, loosening of a tooth, or numbness or a feeling of heaviness in the jaw. These could be signs and symptoms of bone damage in the jaw (osteonecrosis).

Some side effects are more common in elderly patients. These include blood clots in the arteries, which can lead to a stroke or heart attack. In addition, elderly patients have a higher risk of a reduction in the number of white cells in the blood (which increases the risk of infections) and cells that help the blood clot (which can lead to bleeding or bruising more easily than normal). Other side effects reported with a higher frequency in elderly patients were diarrhoea, nausea or sickness, headache and fatigue.

There have been reports of abnormal tube-like connections between internal organs and skin or other tissues that are not normally connected.

There have been very rare reports of patients developing a hole in the septum of the nose, the structure that separates the nostrils. Symptoms may include nose bleeds, nasal congestion or infection, or whistling sounds when breathing.

VEGZELMA is not approved for use in the eye. The following side effects may also occur if VEGZELMA is injected directly into the eye:

- infection (some cases leading to blindness)
- eye pain, redness of the eye
- small particles or spots in your vision (floaters)
- seeing bright flashes of light with floaters, progressing to a loss of sight
- bleeding in the eye
- cataracts, leading to surgery of the eye lens
- serious side effects affecting other organs, which can be severe or life-threatening and lead to hospitalisation, e.g. stroke.

This is not a complete list of all possible side effects. 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.

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## After receiving VEGZELMA

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### **Storage**

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

### **Disposal**

**VEGZELMA is for single use only.**

The vials should be used once only and any remaining contents should be discarded.

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## Product description

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### **Availability**

VEGZELMA is available in 100 mg/4 mL and 400 mg/16 mL single-dose vials.

### **What VEGZELMA looks like**

VEGZELMA is a clear to slightly opaque, colourless to pale brown solution.

### **Ingredients**

#### **Active ingredient**

bevacizumab

#### **Inactive ingredients**

trehalose, monobasic sodium phosphate monohydrate, dibasic sodium phosphate, polysorbate 20, water for injections

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## Distributor

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VEGZELMA is distributed by:

Celltrion Healthcare New Zealand  
Limited 103 Carlton Gore Road,  
Newmarket,  
Auckland 1023  
NEW ZEALAND

Phone: 0800 838 899

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