VEGZELMA

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 VEGZELMA?

VEGZELMA contains the active ingredient bevacizumab. VEGZELMA is used to treat:

- brain tumours resistant to previous treatments
- metastatic (spreading) cancer of the large bowel (i.e. in the colon or rectum), breast or cervix in combination with chemotherapy agents
- 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
- kidney cancer (renal cell cancer) in combination with interferon therapy (Roferon-A®).

For more information, see Section 1. Why am I using VEGZELMA? in the full CMI.

2. What should I know before I use VEGZELMA?

Do not use if you have ever had an allergic reaction to VEGZELMA 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 use VEGZELMA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VEGZELMA 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 VEGZELMA?

- Dose depends on your body weight and the type of cancer to be treated.
- VEGZELMA solution is prepared by a health care professional.
- VEGZELMA is given by infusion into a vein (intravenous infusion) by a health care professional.

More instructions can be found in Section 4. How do I use VEGZELMA? in the full CMI.

5. What should I know while using VEGZELMA?

Things you should 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 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 need to undergo an invasive dental treatment or dental surgery, in particular when you are also receiving or have received a bisphosphonate (for example medicines containing ibandronate sodium, zoledronic acid or disodium pamidronate) • 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 should not do	• Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.
Driving or using machines	• Be careful driving or operating machinery until you know how VEGZELMA affects you.
Looking after your medicine	• VEGZELMA will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2° to 8°C.

For more information, see Section 5. What should I know while using VEGZELMA? in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: stomach cramps or pains, severe or bloody diarrhoea, bleeding from stomach or intestines which may look like coffee grounds or black sticky bowel motions (stools), nausea and vomiting; including vomiting blood or material that looks like coffee grounds, 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), severe body pain including headaches, loss of control of your bladder or bowels; passage of wind or bowel motions through the vagina, severe bleeding, problems with your wounds healing after surgery, confusion, seizures (fits), feeling of numbness or tingling in hands or feet, dry mouth in combination with thirst and/or reduced or darkened urine, abscesses (pus-filled sores), falling asleep or fainting, problems with the heart with breathing difficulties, chest pain, increase in heart rate (pulse), shortness of breath.

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.

VEGZELMA

Active ingredient(s): *bevacizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VEGZELMA. **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 VEGZELMA.**

Where to find information in this leaflet:

1. Why am I using VEGZELMA?

VEGZELMA contains the active bevacizumab. VEGZELMA is a biosimilar medicine to AVASTIN®. The evidence for comparability supports the use of VEGZELMA for the treatment of:

- brain tumours resistant to previous treatments
- metastatic (spreading) cancer of the large bowel (i.e. in the colon or rectum), breast or cervix in combination with chemotherapy agents
- 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
- kidney cancer (renal cell cancer) 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.

2. What should I know before I use VEGZELMA?

Warnings

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. **the package is torn or shows signs of tampering**
4. **the expiry date (EXP) 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 and adolescents.

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

Check with your doctor if you:

1. **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
   - heart disease
   - history of diabetes
2. **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.
3. **you have had a blocked lung artery (pulmonary**

embolism)
VEGZELMA may increase the risk of recurrence

4. **you have ever received anthracyclines (e.g. doxorubicin), a specific type of chemotherapy used to treat some cancers, or have had radiotherapy to your chest VEGZELMA can increase the risk of developing a weak heart.**
5. **if you have or have had pain in the mouth, teeth and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth tell your doctor immediately.**

   You may be advised to have a dental check-up before you start treatment with VEGZELMA.
6. **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. VEGZELMA can also increase the risk of fatigue, hair loss, reduce the number of white cells in the blood and cells which help blood clot, inflammation of the mouth or throat, high blood pressure and a feeling of numbness or tingling in the hands or feet in patients older than 65 years of age compared with younger patients.
7. **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.

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.

If you become pregnant while you are being treated with VEGZELMA, immediately inform your doctor.
Do not use VEGZELMA if you are pregnant.
VEGZELMA may cause damage to your unborn baby.
VEGZELMA may interfere with your ability to become pregnant. Your doctor will advise you of your options prior to starting treatment.
You should use contraception during treatment with VEGZELMA and for at least 6 months after your last dose. Your doctor will advise you about using contraception during treatment with VEGZELMA.
You should not breast-feed while being treated with VEGZELMA and for at least 6 months after the last dose.
VEGZELMA may interfere with the growth and development of your baby.

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.

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

Tell your doctor if you have recently received, or are receiving, a bisphosphonate (for example medicines containing ibandronate sodium, zoledronic acid or disodium pamidronate).

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VEGZELMA.

4. How do I use VEGZELMA?

How much to take

- VEGZELMA solution is prepared by a health care professional.
- VEGZELMA is given by infusion into a vein (intravenous infusion) by a health care 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.
- 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.

How long is it 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 forget to use VEGZELMA

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

If you use too much VEGZELMA

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

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 using VEGZELMA?

Things you should 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 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 need to undergo an invasive dental treatment or dental surgery, in particular when you are also receiving or have received a bisphosphonate (for example medicines containing ibandronate sodium, zoledronic acid or disodium pamidronate)

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.

Call your doctor straight away if you:

- Do not feel well while being treated with VEGZELMA.
- Become pregnant while using VEGZELMA.

Remind any doctor, dentist or pharmacist you visit that you are using VEGZELMA.

Things you should not do

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

Driving or using machines

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

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

Looking after your medicine

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

Keep it where young children cannot reach it.

When to discard your medicine

VEGZELMA is for single use only.

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

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.

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

Less serious side effects

Less serious side effects	What to do
• high blood pressure • body pain • pain, redness and/or swelling of your hands and/or the soles of your feet that has affected your normal activities (hand-foot syndrome) • muscle and joint pain • lack of energy or tiredness • diarrhoea; constipation or rectal bleeding • inflammation of the mouth or swollen/stiff neck • sore mouth; mouth ulcers; cold sores • loss of appetite, change in sense of taste • shortness of breath • nose bleed; runny or blocked nose • dry skin; rash; flaking, swelling or redness of the skin or change in skin colour • numbness or weakness of the arms and legs • blurred vision or other problems with the eye (including increased production of tears) • dizziness; headache • signs of infection such as swelling, redness and increased temperature, fever, chills, shivering, sore throat or mouth ulcers • bleeding or bruising more easily than normal • changes in your voice or hoarseness • difficulty speaking • loss of body weight • abdominal, pelvic, rectal or back pain	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **[Insert appropriate action]**

• ruptured aneurysm (may include sudden, extremely severe headache, nausea, vomiting, stiff/ swollen neck, vision trouble) • artery dissection (may include fainting, a hoarse voice, hiccups, hearing loss, problems with balance)	

Serious side effects

Serious side effects	What to do
• stomach cramps or pains • severe or bloody diarrhoea • bleeding from stomach or intestines which may look like coffee grounds or black sticky bowel motions (stools) • nausea and vomiting; including vomiting blood or material that looks like coffee grounds • 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) • severe body pain including headaches • loss of control of your bladder or bowels; passage of wind or bowel motions through the vagina • severe bleeding • problems with your wounds healing after surgery • confusion • seizures (fits) • feeling of numbness or tingling in hands or feet • dry mouth in combination with thirst and/or reduced or darkened urine • abscesses (pus-filled sores) • falling asleep or fainting • problems with the heart with breathing difficulties • chest pain • increase in heart rate (pulse) • shortness of breath	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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 a heart attack. In addition, elderly patients have a higher risk of a reduction in the number of white cells in the blood and cells that help the blood clot, which can lead to infections and bleeding or bruising more easily than normal. Other side effects reported with a higher frequency in elderly patients were diarrhoea, nausea or sickness, headache, hair loss, inflammation of the mouth and throat, a feeling of numbness or tingling in the hands or feet and fatigue.

There have been reports of abnormal tube-like connections (fistulae) between internal organs and skin or other tissues that are not normally connected. You may have an increased risk of fistulae forming between the vagina and any part of the gastro-intestinal system if you are being treated with VEGZELMA for cancer of the cervix.

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 or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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. 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 VEGZELMA contains

Active ingredient (main ingredient)	Bevacizumab
Other ingredients (inactive ingredients)	• trehalose dihydrate • monobasic Sodium Phosphate monohydrate • dibasic sodium phosphate • polysorbate 20 • water for injections

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

What VEGZELMA looks like

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

VEGZELMA is available as 100 mg and 400 mg single-dose vials.

100 mg/4 mL AUST R 398631

400 mg/16 mL AUST R 398632

Who distributes VEGZELMA

Celltrion Healthcare Australia Pty Ltd
Suite 13-03, 31 Market Street,
Sydney NSW 2000, Australia

Phone: 1800 325 228

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