

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 being given MVASI?

MVASI contains the active ingredient bevacizumab. It is used to treat some cancers in the brain, lung, bowel, kidney, breast, or female reproductive system. For more information, see Section [1. Why am I receiving MVASI?](#) in the full CMI.

2. What should I know before I am given MVASI?

Read this leaflet carefully before you use MVASI and keep it with the medicine. Check the list of ingredients at the end of the CMI. Do not use MVASI if you have ever had an allergic reaction to any of the ingredients.

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 MVASI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MVASI 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 I be given MVASI?

You will be given MVASI as an infusion (slow injection or "drip") into a vein every 2 to 3 weeks, for as long as you need it.

The infusion usually takes between 30-90 minutes.

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

5. What should I know while being treated with MVASI?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are being treated with MVASI• Be sure to keep all of your appointments with

	<p>your doctor so that your progress can be checked</p> <ul style="list-style-type: none"> ● Tell your doctor immediately if you become pregnant or are breastfeeding during treatment ● Tell your doctor if you: <ul style="list-style-type: none"> ○ are planning to have surgery or have a wound that is not healing properly or ○ need to undergo an invasive dental treatment or dental surgery or ○ feel MVASI is not helping your condition
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not take any other prescription medicines without first checking with your doctor or pharmacist
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how MVASI affects you

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

6. Are there any side effects?

Common side effects include weakness, pain, headache, bleeding, nose bleeds, nausea, vomiting, diarrhoea, loss of appetite, and mouth sores, rectal bleeding, bleeding or bruising more easily than normal, urinary tract infection, foamy urine, fainting.

Serious side effects include serious bleeding, severe high blood pressure, holes in the stomach or intestine, stroke, severe heart failure or other heart problems, nervous system or vision problems, shortness of breath, difficulty breathing, or fistula (abnormal connection between two body parts). 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.

MVASI[®] (em-vah'-see)

Active ingredient(s): *bevacizumab* (pronounced bev-a-SIZZ-u-mab)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I receiving MVASI?

MVASI contains the active ingredient bevacizumab. MVASI is a biosimilar medicine to AVASTIN[®]. It has been assessed to be as safe and effective as the reference product and provides the same health outcomes. Avastin[®] is not available in Australia.

MVASI is used to treat:

- Brain tumours that are resistant to previous treatments.
- Metastatic cancers of the large bowel (i.e., in the colon or rectum), breast or cervix in combination with chemotherapy agents. Metastatic means the cancer has spread to other parts of the body from where it started.
- 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 in combination with interferon therapy (Roferon-A®).

All cancers need a blood supply to be able to survive and grow. Bevacizumab targets a protein called vascular endothelial growth factor (VEGF). This protein helps cancer cells to grow blood vessels, so they can get nutrients and oxygen from the blood. When MVASI binds to VEGF it disrupts the blood supply to the tumour, stopping or slowing down its growth.

2. What should I know before I am given MVASI?

Warnings

MVASI is not approved for use in the eye.

Based on your age, especially if you are 65 years or older, or on your general health, your doctor will discuss your ability to tolerate MVASI.

- MVASI 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.
- MVASI can also increase the risk of side effects in patients older than 65 years of age compared with younger patients.

You must not be given MVASI if you:

- are allergic to bevacizumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use it. 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.
- have had an allergic reaction to any proteins that are of Chinese hamster origin or to other recombinant human or humanised antibodies.
- are a child or adolescent. The safety and effectiveness in children and adolescents have not been established.

Check with your doctor if you:

- have or previously have had any of the following:
 - **radiation therapy or radiotherapy** (treatment with high energy x-rays)

- **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
- **blood clots or stroke**, or if you are taking medicine to prevent blood clots (e.g. warfarin) or if anyone in your family suffers from bleeding problems
- **heart disease**
- **diabetes**
- **major surgery within the last 28 days or have a wound that has not healed properly**. MVASI can cause an increased risk of post-operative bleeding or problems with wound healing.
- **blocked lung artery** (pulmonary embolism). MVASI may increase the risk of recurrence
- received **anthracyclines** (e.g., doxorubicin) or have had radiotherapy to your chest. Anthracyclines are a specific type of chemotherapy used to treat some cancers. MVASI can increase the risk of developing a weak heart.
- **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 MVASI
- **allergies** to any other medicines, foods, dyes or preservatives
- **other health problems.**

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

Do not use MVASI if you are pregnant. MVASI may cause damage to your unborn baby.

Check with your doctor if you are pregnant or intend to become pregnant. MVASI may interfere with your ability to become pregnant. Your doctor will advise you of your options prior to starting treatment.

If you are a woman of childbearing potential, use suitable methods of contraception during treatment with MVASI and for at least 6 months after your last dose. Your doctor can advise about using contraception during treatment with MVASI.

Immediately inform your doctor if you become pregnant while you are being treated with MVASI.

Breastfeeding

Do not breastfeed while being treated with MVASI and for at least 6 months after the last dose. MVASI may interfere with the growth and development of your baby. Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Tell your healthcare professional if you:

- have recently received, or are receiving a bisphosphonate (medicine used in preventing or treating bones that are weak and likely to break), such as ibandronate sodium, zoledronic acid or disodium pamidronate.
- are taking other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Read the CMI leaflets of all medicines you take in combination with MVASI. This will help you understand the information related to those medicines.

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

4. How will I be given MVASI?

When you will be given MVASI

MVASI will be given either once every 2 weeks or once every 3 weeks depending on the type of cancer to be treated.

How much MVASI you will be given

Your doctor will prescribe your dose. The dose depends on your body weight, general health and the type of cancer to be treated.

How MVASI is given

Your healthcare provider will give you MVASI as an infusion into a vein ("drip"), through a tube, using an infusion pump. The first dose is usually given over 90 minutes. If it is well tolerated, the later infusion times may be shortened to between 30 to 60 minutes.

How long MVASI 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 MVASI.

If you have been given too much MVASI

As MVASI is given to you under the supervision of your doctor, it is unlikely that you will receive too much. However, if you experience severe side effects, like a severe migraine, after being given this medicine, tell

your doctor or nurse immediately. You may need urgent medical attention.

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.

5. What should I know while being treated with MVASI?

Things you should do

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:

- become pregnant during treatment with MVASI, or plan to start a family in the near future.
- are breastfeeding while being treated with MVASI.
- are planning to have surgery.
- You have a wound that is not healing properly.
- 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)
- feel MVASI is not helping your condition.

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

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 MVASI affects you.

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

Looking after your medicine

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

Disposal

MVASI is for single use only.

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

MVASI must not be used 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 MVASI 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 MVASI or due to other medicines.

MVASI 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.

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
<p>Lungs and upper airways</p> <ul style="list-style-type: none">• changes in your voice or hoarseness• nose bleed; blocked or runny nose• difficulty speaking	<p>Speak to your doctor if you have any of these less serious side effects and they worry you</p>

Less serious side effects	What to do
<p>Ears, eyes and mouth</p> <ul style="list-style-type: none"> ● inflammation of the mouth ● sore mouth; mouth ulcers; cold sores ● blurred vision or other problems with the eye (including increased production of tears) <p>Metabolism and nutrition</p> <ul style="list-style-type: none"> ● loss of appetite <p>Muscles and joints</p> <ul style="list-style-type: none"> ● swollen/stiff neck ● muscle and joint pain <p>Brain and nervous system</p> <ul style="list-style-type: none"> ● change in sense of taste ● dizziness ● numbness or weakness of the arms and legs <p>Gut and digestion</p> <ul style="list-style-type: none"> ● diarrhoea; constipation or rectal bleeding <p>Skin and nails</p> <ul style="list-style-type: none"> ● dry skin; rash; flaking, swelling or redness of 	

Less serious side effects	What to do
<p>the skin or change in skin colour</p> <ul style="list-style-type: none"> ● pain, redness and/or swelling of your hands and/or the soles of your feet that has affected your normal activities (hand-foot syndrome) <p>Blood</p> <ul style="list-style-type: none"> ● high blood pressure ● bleeding or bruising more easily than normal <p>Body as a whole</p> <ul style="list-style-type: none"> ● headache ● general body pain ● lack of energy or tiredness ● fever; chills; shivering ● loss of body weight <p>Stomach and abdominal region</p> <ul style="list-style-type: none"> ● abdominal, pelvic, anal or back pain 	
<p>Infections and infestations</p> <ul style="list-style-type: none"> ● signs of infection such as swelling, redness and 	<p>Tell your doctor if you experience any of these side effects.</p>

Less serious side effects	What to do
<p>increased temperature, fever, chills, sore throat or mouth ulcers</p> <p>Body as a whole</p> <ul style="list-style-type: none"> ● sudden headache and nausea (may include stiff/swollen neck, vision trouble) ● hypersensitivity and/or infusion reactions (reactions related to your injection of the medicine) <p>Stomach and abdominal region</p> <ul style="list-style-type: none"> ● sudden pain in the stomach or back (may include fainting, hiccups, hearing loss, problems with balance) <p>Ears, eyes and mouth</p> <ul style="list-style-type: none"> ● 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 	

Less serious side effects	What to do
<p>bone damage in the jaw (osteonecrosis).</p> <ul style="list-style-type: none"> ● nose bleeds, nasal congestion or infection, or whistling sounds when breathing. You may have developed a very rare side effect of a hole in the septum of the nose, the structure that separates the nostrils. <p>Kidney and urinary related:</p> <ul style="list-style-type: none"> ● Urinary tract infection ● Foamy urine 	

Serious side effects

Serious side effects	What to do
<p>Lungs and upper airways</p> <ul style="list-style-type: none"> ● bleeding in the lungs, including coughing or spitting blood <p>Heart</p> <ul style="list-style-type: none"> ● problems with the heart with breathing difficulties 	<p>Tell your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● increase in heart rate (pulse) <p>Ears, eyes and mouth</p> <ul style="list-style-type: none"> ● dry mouth in combination with thirst and/or reduced or darkened urine <p>Brain and nervous system</p> <ul style="list-style-type: none"> ● confusion ● seizures (fits) ● falling asleep or fainting ● sudden, extremely severe headache, nausea and vomiting <p>Gut and digestion</p> <ul style="list-style-type: none"> ● 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 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● loss of control of your bladder or bowels; passage of wind or bowel motions through the vagina <p>Blood</p> <ul style="list-style-type: none"> ● pain, redness, swelling and warmth over a vein which may suggest deep vein thrombosis (blood clots in the veins of legs) ● severe bleeding ● Signs of a blood clot, such as sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling in the arms and legs <p>Body as a whole</p> <ul style="list-style-type: none"> ● severe body pain including headaches ● problems with your wounds healing after surgery 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● feeling of numbness or tingling in hands or feet ● abscesses (pus-filled sores) ● sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness (anaphylactic shock) <p>Stomach and abdominal region</p> <ul style="list-style-type: none"> ● stomach cramps or pains ● a sudden pain in the back or stomach or feeling weak, numb or tingly down one side, like a stroke. 	

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 MVASI for cancer of the cervix.

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 MVASI contains

Active ingredient (main ingredient)	bevacizumab
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• 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 MVASI looks like

MVASI is a clear to slightly opaque, colourless to pale yellow solution.

MVASI is supplied in a glass vial. Each pack contains one vial.

MVASI bevacizumab 100 mg/4 mL injection concentrated injection vial (AUST R 297455)

MVASI bevacizumab 400 mg/16 mL injection concentrated injection vial (AUST R 297456)

Who distributes MVASI

Amgen Australia Pty Ltd

Level 11, 10 Carrington St

Sydney NSW 2000

Ph: 1800 803 638

www.amgenmedinfo.com.au

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