

ABEVMY®

bevacizumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ABEVMY 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 ABEVMY 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.

What ABEVMY is used for

ABEVMY 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®).

ABEVMY contains the active ingredient bevacizumab.

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

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

ABEVMY 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 ABEVMY 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, lung, kidney and cervix.

Your doctor may have prescribed ABEVMY for another purpose.

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

This medicine is not addictive.

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

Before you are given ABEVMY

When you must not be given it

Do not use ABEVMY if:

- 1. you have had an allergic reaction to ABEVMY 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 ABEVMY, talk to your doctor.

Do not give ABEVMY to children and 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 ABEVMY if you are pregnant. ABEVMY may cause damage to your unborn baby.

You should use contraception during treatment with ABEVMY and for at least 6 months after your last dose. If you become pregnant while you are being treated with ABEVMY, immediately inform your doctor.

Your doctor will advise you about using contraception during treatment with ABEVMY.

2. you plan to start a family in the future

ABEVMY 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 ABEVMY and for at least 6 months after the last dose. ABEVMY 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
- heart disease
- history of diabetes

5. you have had major surgery within the last 28 days or have a wound that has not healed properly

ABEVMY can cause an increased risk of post-operative bleeding or problems with wound healing.

6. you have had a blocked lung artery (pulmonary embolism)

ABEVMY may increase the risk of recurrence

7. you have ever received an anthracycline (a specific type of chemotherapy used to treat some cancers), such as doxorubicin, or if you have ever had radiotherapy to your chest, because ABEVMY can increase the risk of developing a weak heart after these treatments.

8. 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 ABEVMY.

9. you are 65 years of age or older

ABEVMY 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. ABEVMY 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.

10. 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 ABEVMY.

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 ABEVMY.

Some medicines may be affected by ABEVMY, 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 ABEVMY.

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

How ABEVMY is given

How it is given

ABEVMY solution is prepared by a health care professional.

ABEVMY 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.

How much is given

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

If you have been given too much ABEVMY you may develop a severe migraine. If this happens

tell your health care professional immediately.

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 miss a dose

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

While you are being treated with ABEVMY

Things you must do

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

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

Tell your doctor immediately if you are breast-feeding while being treated with ABEVMY.

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 ABEVMY 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 ABEVMY affects you.

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

Side effects

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

ABEVMY helps most people with brain tumours and cancer of the large bowel (i.e. colon or rectum), breast, lung, kidney, ovary/fallopian tube (which can extend to the lining of surrounding organs such as stomach, liver) and cervix 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 ABEVMY against the benefits they expect it will have for you.

Because ABEVMY 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 ABEVMY or due to other medicines.

ABEVMY 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 the following lists of 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
- 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, anal or back pain

- 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)

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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

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 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 ABEVMY 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.

ABEVMY is not approved for use in the eye. The following side effects may also occur if ABEVMY 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.

After receiving ABEVMY

Storage

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

Disposal

ABEVMY is for single use only.

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

Product description

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

What it looks like

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

Ingredients

ABEVMY contains bevacizumab as the active ingredient.

Inactive ingredients:

- trehalose dihydrate
- monobasic sodium phosphate dihydrate
- dibasic sodium phosphate
- polysorbate 20
- water for injections
- sodium hydroxide
- ortho phosphoric acid

Supplier

ABEVMY is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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Australian registration numbers:

100 mg/4 mL AUST R 334816

400 mg/16 mL AUST R 334814

ABEVMY® is a Viatris company trade mark

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