

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

#### **Pr**ABEVMY®

(pronounced) a-bev-mai

#### **bevacizumab for injection**

Read this carefully before you start taking ABEVMY and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ABEVMY.

ABEVMY is a biosimilar biologic drug (biosimilar) to the reference biologic drug <sup>Pr</sup>AVASTIN®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

#### **Serious Warnings and Precautions**

##### **Eye disorders**

ABEVMY was not developed to be injected in the eye and should be used as authorized. Side effects affecting the eye and the body as a whole were seen in some patients who had ABEVMY injected in their eye(s).

##### **Gastrointestinal Perforations**

ABEVMY treatment can cause gastrointestinal perforation (hole in the stomach or bowel) which can be fatal. ABEVMY treatment should be stopped if this happens. Gastrointestinal perforation can happen at any time during treatment: symptoms include abdominal pain, constipation and vomiting.

##### **Wound Healing Complications**

ABEVMY treatment can cause wound dehiscence (wounds opening and not healing), which can be fatal. ABEVMY treatment should be stopped if this happens and for one month after having surgery or until the wound is fully healed. ABEVMY should be stopped at least 28 days before elective surgery.

##### **Hemorrhage**

Treatment with ABEVMY can result in serious or fatal bleeding, including coughing up blood, bleeding in the stomach, vomiting of blood, bleeding in the brain, nosebleeds, and vaginal bleeding. These events occurred up to 5 times more often in people who received bevacizumab compared to patients who received only chemotherapy. People who have recently coughed up blood (greater than or equal to a half teaspoon of red blood) or have serious bleeding should not receive ABEVMY. Treatment with ABEVMY should be permanently stopped if serious bleeding occurs (i.e. requiring medical attention).

#### **What is ABEVMY used for?**

- **Metastatic Colorectal Cancer:** ABEVMY is used in combination with a specific type of chemotherapy (intravenous 5-fluorouracil [5-FU]-based chemotherapy) for treatment of

people diagnosed with metastatic colorectal cancer for the first time. Metastatic colorectal cancer is cancer of the colon or rectum that has spread to other organs in the body.

- **Metastatic Lung Cancer:** ABEVMY is used in combination with a specific type of chemotherapy (carboplatin and paclitaxel) for the treatment of people diagnosed with metastatic non small cell lung cancer. Metastatic non small cell lung cancer is cancer of the lungs that has spread to other organs in the body.
- **Recurrent Platinum-Resistant Ovarian Cancer:** ABEVMY is used in combination with a specific type of chemotherapy (paclitaxel, topotecan, or pegylated liposomal doxorubicin) for the treatment of people diagnosed with recurrent, platinum-resistant, epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens. Recurrent platinum-resistant ovarian cancer is the type of cancer that progresses within 6 months after the last time the patient responded to a chemotherapy regimen containing a platinum agent.
- **Recurrent Glioblastoma:** ABEVMY is used in combination with lomustine (a specific type of chemotherapy) for the treatment of patients with a particular type of brain cancer called glioblastoma in which the cancer reoccurred after a previous treatment.

### **How does ABEVMY work?**

ABEVMY is not chemotherapy but is given in combination with a specific type of chemotherapy. ABEVMY is a monoclonal antibody. While chemotherapy attacks the tumour directly, ABEVMY attacks the blood vessels that surround the tumour.

In order to grow and spread, tumours need a constant supply of oxygen and other nutrients. Tumours get this supply by creating their own network of blood vessels. This process is called angiogenesis (an'-jee-o-jen'-i-sis). ABEVMY works by blocking angiogenesis. By preventing the growth of new blood vessels, ABEVMY helps starve the tumour of oxygen and other nutrients. This makes it hard for the tumour to grow.

### **What are the ingredients in ABEVMY?**

The medicinal ingredient is called bevacizumab

The non-medicinal ingredients are (in alphabetical order): ortho phosphoric acid, polysorbate 20, Sodium dihydrogen phosphate dehydrate, sodium hydroxide, sodium phosphate dibasic anhydrous,  $\alpha$ ,  $\alpha$  – trehalose dehydrate, water for injection

### **ABEVMY comes in the following dosage forms:**

ABEVMY is available as single use vials in the presentations listed below:

- 100 mg/4 mL (25 mg/mL)
- 400 mg/16 mL (25 mg/mL)

The vial stopper is not manufactured with natural rubber latex.

### **Do not use ABEVMY if:**

ABEVMY should not be used by people who are allergic to it or any of its ingredients or by

people whose cancer has spread to their central nervous system (to their brain or spine). ABEVMY should not be taken for at least 28 days following surgery.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ABEVMY. Talk about any health conditions or problems you may have, including if you:**

- have high blood pressure
- plan to have surgery or have had surgery in the last 28 days
- have ever had a heart attack or stroke
- are pregnant or planning to become pregnant
- are breast feeding
- have any allergies to this drug or its ingredients
- have any illnesses or diseases affecting your kidneys;
- have heart failure or weakened heart muscles
- have ever coughed up blood or observed abnormal vaginal bleeding
- are diabetic.

**Other warnings you should know about:**

ABEVMY should not be used during pregnancy as it may cause harm to your unborn baby. Therefore, you should use effective methods of contraception while taking ABEVMY and for at least 6 months after your last dose of Bevacizumab. If you become pregnant during treatment with ABEVMY tell your doctor immediately.

ABEVMY may affect the hormonal balance of women and their ability to get pregnant as a result of ovarian failure. If you are a woman of reproductive potential, talk to your doctor before starting treatment with ABEVMY.

If you develop headache, vision problems, dizziness, or change in mental status (for example, confusion) contact your doctor immediately.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with ABEVMY:**

Drugs that may interact with ABEVMY include: irinotecan and sunitinib malate. Your doctor may adjust the dose of irinotecan if you have side effects known to be related to it. The safety and effectiveness of ABEVMY in combination with sunitinib malate has not been established, therefore this combination is not recommended.

Tell your doctor if you are using platinum- or taxane-based therapies for lung. These therapies in combination with ABEVMY may increase the risk of severe side effects.

The interaction of ABEVMY in combination with EGFR monoclonal antibodies has not been studied, therefore this combination is not recommended.

**How to take ABEVMY:**

ABEVMY is given intravenously (through a needle placed in a vein in the arm, hand, or through

a central line).

### **Usual dose:**

#### Metastatic Colorectal Cancer

The usual dose of ABEVMY is based on your weight in kg (5 mg/kg) and it is given once every 14 days for as long as your physician recommends therapy.

#### Metastatic Lung Cancer

The usual dose of ABEVMY is based on your weight in kg (15 mg/kg) and on the specific type of chemotherapy given along with the ABEVMY. ABEVMY is given once every 3 weeks for as long as your physician recommends therapy.

#### Ovarian Cancer (Platinum-resistant recurrent disease)

The usual dose of ABEVMY is based on your weight in kg (10 mg/kg or 15 mg/kg). ABEVMY is given once every 2 weeks or 3 weeks for as long as your physician recommends therapy. Your doctor will prescribe a dose and schedule of ABEVMY that is right for you, based on if and what type of chemotherapy you are also receiving.

#### Recurrent Glioblastoma

The usual dose of ABEVMY is based on your weight in kg (10 mg/kg). ABEVMY is given once every 2 weeks in combination with lomustine every 6 weeks for as long as your physician recommends therapy. The dose of lomustine in the first treatment is 90 mg per square metre of your body surface area (mg/m<sup>2</sup>), up to a maximum dose of 160 mg. It can be increased to 110 mg/m<sup>2</sup>, up to a maximum of 200 mg, from the second treatment onwards. The increase dose of lomustine after the first treatment will be determined by your doctor based on your blood work.

The first time ABEVMY is given, it will take about 90 minutes. Once your doctor has made sure that you have no problems with the ABEVMY infusions, (i.e. after the first or second infusion), subsequent infusions may require less time, usually about 30 or 60 minutes.

### **Overdose:**

**If you think you have taken too much ABEVMY, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.**

In addition to the possible side-effects listed below, an overdose may cause a severe headache.

### **Missed Dose:**

If you miss a dose of ABEVMY, your doctor will decide when you should receive your next dose.

### **What are possible side effects from using ABEVMY?**

These are not all the possible side effects you may feel when taking ABEVMY. If you experience any side effects not listed here, contact your healthcare professional.

Like all medications, ABEVMY can cause some unwanted side effects. The following side effects were seen in clinical trials when ABEVMY in combination with chemotherapy or

ABEVMY alone was given to patients:

Very Common (more than 1 in 10 patients):

- High blood pressure
- Diarrhea, vomiting
- Abdominal pain
- Constipation
- Nausea
- Lack of energy or strength
- Loss of appetite
- Pain (including joint pain)
- Bleeding (from the nose or rectum)
- Sores in the mouth
- Shortness of breath
- Runny nose
- Dry, scaling skin or changes in skin colour
- Changes in the sense of taste
- Eye problems (for example: excessive tearing, blurred vision, an experience of discomfort or pain to the eyes due to light exposure)
- A decrease in certain white blood cells in the blood that help fight off infection
- Decrease in the number of red blood cells [anemia]
- Difficulty in sleeping
- Fever, chills or excessive sweating
- Headache
- Abnormal urine test (protein in the urine)
- Tingling sensation or numbness in toes and fingers
- Bronchitis (an inflammation of the main air passages to the lungs)
- Bruising
- Change in moods
- Infections (mouth, throat, sinus, lungs or urine infections)
- Excess of sugar in the blood
- Weight loss
- Widening of the blood vessels
- Low levels of sodium and magnesium in the blood
- Coughing
- Tiredness

Common (less than 1 in 10 patients but more than 1 in 100 patients):

- Pain (including muscle pain, chest pain, heart pain (angina), back pain, and pain in the pelvis and anal regions)
- Stroke/heart attack
- Blood clots
- Perforation of the gut (hole in the stomach or bowel)
- Altered voice such as hoarseness
- Swelling and numbness of the hand and feet
- Urinary (bladder or kidney) infection
- Infections of the skin or deeper layers under the skin
- Fistula (abnormal tube like connection between internal parts of the body that are not

normally connected) such as between the stomach and intestines (gastrointestinal fistula), in patients with metastatic colorectal cancer and platinum resistant ovarian cancer, and between the vagina and the gut in patients with cervical cancer (unauthorized use)

- Allergic reactions
- Nephrotic syndrome (a type of kidney disorder)

Uncommon (less than 1 in 100 patients but more than 1 in 1000 patients):

- Non-gastrointestinal perforations and fistulae (abnormal holes or tubes in areas of the body other than the gastrointestinal tract)
- Posterior Reversible Encephalopathy Syndrome (PRES) a syndrome characterized by headache, confusion, seizures and visual loss

Rare (less than 1 in 1000 patients but more than 1 in 10,000 patients):

- Tracheoesophageal fistula (abnormal tube like connection between internal parts of the body that are not normally connected) such as between the trachea (or windpipe) and esophagus (tube connecting the mouth to the stomach)
- Severe bacterial infection of the skin and soft tissue (necrotizing fasciitis)
- Bleeding (in the brain) Frequency unknown:
- Ulcers in the stomach and bowel
- Jaw bone damage resulting from poor blood supply to the jaw bone
- Perforation in the gallbladder (hole in the digestive organ that stores bile)

If your blood pressure increases while you are taking ABEVMY, it is important to contact your doctor.

Changes in your blood and urine tests done by your doctor may occur while you are receiving ABEVMY. These changes may include a lower white cell count, and protein in the urine. Your doctor will discuss these results with you.

Elderly patients (65 years or older) have a greater risk of developing the following side effects: blood clots (that may lead to stroke or heart attack), a decrease in certain white blood cells and platelets, protein in the urine, diarrhea and fatigue.

Outside of the authorized use of ABEVMY for cancer treatment, the following side effects may occur when ABEVMY is injected directly into the eye (unauthorized use):

- Infection or inflammation of the eye globe, which may lead to permanent blindness
- Redness of the eye, small particles or spots in your vision (floaters), eye pain, which may lead to permanent blindness
- Seeing flashes of light with floaters, progressing to a loss of some of your vision
- Increased eye pressure
- Bleeding in the eye
- Surgery of the eye lens due to cataract
- Other serious side effects affecting other organs, which may be severe and lead to hospitalisation, e.g. heart attack, stroke, and high blood pressure

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON (more than 1 in 10 patients)</b> <b>High blood pressure</b> You may not experience any symptoms, but possible symptoms associated with high blood pressure are: headache, blurred vision, fatigue, irregular fast, hard heartbeats		√	
Bleeding from the nose that lasts for more than 10-15 minutes and cannot be stopped			√
Diarrhea		√	
Vomiting		√	
Constipation		√	
Bleeding from the rectum or stomach Symptoms include fresh blood in stools and/or dark stools		√	
Decreased number of white blood cells Symptoms could include fever, sore throat, infection		√	
Decreased number of red blood cells in the blood that carry oxygen Symptoms could include feeling of weakness or fatigue in general or during exercise, poor concentration		√	
Pain (chest pain, back pain, abdominal pain, muscle pain, joint pain)		√	
Low blood pressure You may not experience any symptoms, but possible		√	
symptoms associated with low blood pressure are: lightheadedness, dizziness, fainting			
Dilation (widening) of the blood vessels Symptoms may include low blood pressure, dizziness, flushing		√	

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Bronchitis (an inflammation of the main air passages to the lungs)		√	
Excess of sugar in the blood Symptoms may include frequent hunger, frequent thirst, frequent urination		√	
Infections (mouth, throat, sinus, lungs or urine infections)		√	
Weakened heart muscle/loss of the heart's pumping ability (symptoms may include shortness of breath, fatigue, persistent coughing or wheezing, increased heart rate, swelling in the feet or ankles)		√	
Low levels of sodium and magnesium in the blood		√	
Coughing		√	
<b>COMMON</b> (less than 1 in 10 patients but more than 1 in 100 patients) Perforation of the gut (leakage of the bowel) Symptoms include: sudden onset of abdominal pain, abdominal tenderness with vomiting, high fever			√
Allergic reactions Symptoms include difficulty in breathing, chest pain, redness or flushing of the skin, rash, shivering, nausea, vomiting		√	
Blood clots In the deep veins of the leg, symptoms include: pain, swelling, warm to the touch, and tenderness of the leg.		√	
In the lung, symptoms include: shortness of breath, chest pain, light headedness			

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Stroke or heart attack Symptoms of stroke include: sudden loss of speech or numbness of part or all of the body, loss of vision or blurred vision, unexplained dizziness and/or sudden falls. Symptoms of a heart attack include: chest pain with spreading to the left arm, jaw and/or back, shortness of breath			√
Pain in the pelvis and anal regions		√	
Fistula Abnormal tube-like connection between internal organs and skin or other tissues that are not normally connected, including connections between the vagina and the gut in patients with cervical cancer (unauthorized use)			√
Nephrotic syndrome (a type of kidney disorder) Symptoms include swelling in the face, arms, legs, belly area, foamy appearance of urine and poor appetite		√	
<b>UNCOMMON</b> (less than 1 in 100 patients but more than 1 in 1000 patients) Non-gastrointestinal perforations and fistulae Depending on the organs involved the symptoms could be as follows: leakage of urine, abnormal and bad odor in the genital area, abdominal pain, vomiting, fever, gradually increasing/worsening of shortness of breath (dyspnoea), cough, chest pain, yellowish discoloration of the skin etc.		√	√

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Posterior Reversible Encephalopathy Syndrome (PRES) Symptoms include headache, confusion, seizures and visual loss			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

### Storage:

Store in a refrigerator at the recommended temperature of 2 – 8 °C. Do not freeze. Do not shake. Keep vial in the outer carton in order to protect from light.

Keep out of reach and sight of children.

### If you want more information about ABEVMY:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://hc-sc.gc.ca/index-eng.php) (<http://hc-sc.gc.ca/index-eng.php>); Mylan's website [www.mylan.ca](http://www.mylan.ca) or by calling 1-844-596-9526

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