

**CONSUMER INFORMATION**  
**Product Monograph Part III**

**AVASTIN<sup>®</sup>**  
**Bevacizumab**  
**25 mg/mL solution**

**Hoffman-La Roche Limited**

**Submission Control No. 089366**

The Consumer Information Section (Part III) of the Product Monograph for AVASTIN<sup>®</sup> has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on September 9, 2005 and does not necessarily reflect the most current information for the product.

**For the most up-to-date product information, please consult your health care professional.**

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

## PART III: CONSUMER INFORMATION

**Avastin™**  
bevacizumab

This leaflet is part III of a three-part "Product Monograph" published when AVASTIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AVASTIN. Contact your doctor or pharmacist if you have any questions about the drug.

### ABOUT THIS MEDICATION

What the medication is used for:

AVASTIN (pronounced ah-va'-stin) 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.

What it does:

AVASTIN is not chemotherapy but is given in combination with chemotherapy. AVASTIN is a monoclonal antibody. While chemotherapy attacks the tumour directly, AVASTIN 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'-gee-o-jen'-i-sis). AVASTIN works by blocking angiogenesis. By preventing the growth of new blood vessels, AVASTIN helps starve the tumour of oxygen and other nutrients. This makes it hard for the tumour to grow.

When it should not be used:

AVASTIN should not be used by people who are allergic to it or any of its ingredients or to people whose cancer has spread to their central nervous system. AVASTIN should not be taken for at least 28 days following surgery.

What the medicinal ingredient is:

The medicinal ingredient is called bevacizumab.

The nonmedicinal ingredients are:

$\alpha,\alpha$ -trehalose dihydrate, polysorbate 20, sodium phosphate and Water for Injection.

What dosage forms it comes in:

AVASTIN is given intravenously (through a needle placed in a vein in the arm, hand, or through a central line).

### WARNINGS AND PRECAUTIONS

BEFORE you use AVASTIN talk to your doctor or pharmacist if you:

- have high blood pressure;
- have had surgery in the last 28 days;
- have ever had a heart attack or stroke;
- are pregnant or plan to become pregnant;
- are breast feeding;
- have any allergies to this drug or its ingredients;
- have any illnesses or diseases affecting your kidneys.

### INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with AVASTIN include: irinotecan. Your doctor may adjust the dose of irinotecan if you have side effects known to be related to it.

## PROPER USE OF THIS MEDICATION

### Usual dose:

The usual dose of AVASTIN 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. The first time AVASTIN is given, it will take about 90 minutes. After the first or second time, once your doctor makes sure you have no problems with the infusion, treatments with AVASTIN may require less time, usually about 60 or 30 minutes.

### Overdose:

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

### Missed Dose:

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

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, AVASTIN may have some unwanted effects. The following side effects were seen in clinical trials when AVASTIN was given to patients as recommended for metastatic colorectal cancer.

- Diarrhea
- Constipation
- Nausea
- Lack of energy or strength
- Pain
- Loss of appetite
- 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

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

## SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist	
		Only if severe	In all cases
Common	High blood pressure -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 more than 10-15 minutes and cannot be stopped.	✓	
	Diarrhea		✓
	Vomiting		✓
	Constipation		✓
	Abdominal pain		✓
	Pain		✓
	Infection		✓
	Chest Pain		✓
	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		✓
	Bleeding from the rectum or stomach -Symptoms include fresh blood in stools and/or dark stools		✓
Uncommon	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.		✓
	Perforation of the gut (leakage of the bowel) -Symptoms include: sudden onset of abdominal pain, abdominal tenderness with vomiting, high fever.		✓

*This is not a complete list of side effects. For any unexpected effects while taking AVASTIN, contact your doctor or pharmacist.*

## **REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345  
toll-free fax: 866-678-6789  
By email: [cadmp@hc-sc.gc.ca](mailto:cadmp@hc-sc.gc.ca)

By regular mail:  
National AR Centre  
Marketed Health Products Safety and Effectiveness Information Division  
Marketed Health Products Directorate  
Tunney's Pasture, AL 0701C  
Ottawa ON K1A 0K9

***NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.***

## **MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:  
[www.rochecanada.com](http://www.rochecanada.com).

This leaflet was prepared by Hoffmann-La Roche Limited

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