

**PART III: CONSUMER INFORMATION****Pr YERVOY<sup>®</sup> (yur-voi)  
(ipilimumab for injection)**

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

**ABOUT THIS MEDICATION****What the medication is used for:****Skin cancer**

YERVOY (ipilimumab for injection) is a prescription medicine used to treat melanoma (a kind of skin cancer) that has spread or cannot be removed by surgery. It is for the treatment of melanoma in adults

YERVOY may be given in combination with OPDIVO (nivolumab) in adult patients with advanced melanoma who have not been treated.

**Kidney cancer**

YERVOY may be given in combination with OPDIVO (nivolumab) in adult patients with advanced kidney cancer (called renal cell carcinoma) who have not been treated.

If your doctor has prescribed YERVOY in combination with OPDIVO<sup>®</sup> (nivolumab) you should read the leaflets for both medications as they contain different information.

It is not known if YERVOY is safe and effective in children less than 18 years of age.

**What it does:**

YERVOY helps your immune system attack and destroy cancer cells by your immune cells.

**When it should not be used:**

Do not use YERVOY if you

- are allergic to ipilimumab or any other ingredients in YERVOY
- have an active, very severe condition where your immune system attacks your body (life-threatening autoimmune disease)
- have received an organ transplant

**What the medicinal ingredient is:**

The medicinal ingredient in YERVOY is ipilimumab.

**What the important nonmedicinal ingredients are:**

Tris-hydrochloride, sodium chloride, mannitol, diethylene triamine pentaacetic acid (DTPA) and polysorbate 80.

**What dosage forms it comes in:**

YERVOY 50 mg/10 mL (5 mg/mL) and 200 mg/40 mL (5 mg/mL) are supplied in glass vials.

**WARNINGS AND PRECAUTIONS****Serious Warnings and Precautions****Symptoms of serious side effects**

YERVOY acts on your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and some inflammatory conditions may be life-threatening.

YERVOY can cause serious side effects in many parts of your body which can lead to death. These serious side effects may include: inflammation of the intestines (colitis) that can cause tears or holes (perforation) in the intestines; inflammation of the liver (hepatitis) that can lead to liver failure; inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis); inflammation of the nerves that can lead to paralysis (Guillain-Barré syndrome); inflammation of hormone glands (especially the pituitary, adrenal, and thyroid glands) that may affect how these glands work; and inflammation of the eyes. Please see complete Important Safety Information for details on signs and symptoms.

These side effects are most likely to begin during treatment; however, side effects can show up months after your last infusion. It is important to tell your doctor immediately if you have, or develop, any of the symptoms listed under **Serious Side Effects, How Often They Happen and What To Do About Them**.

**BEFORE you use YERVOY talk to your doctor or nurse if you:**

- have an active autoimmune disease, such as ulcerative colitis, Crohn's disease, lupus, or sarcoidosis
- have hepatitis
- take steroids or other medicines that lower your immune response
- had a severe skin reaction with a previous cancer therapy which works with your immune system
- take any medicines that stop your blood from clotting (anticoagulants)
- have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)

**Pregnancy and Breastfeeding:**

- are pregnant or plan to become pregnant. You should not become pregnant while you are getting YERVOY. YERVOY can cause harm or death to your unborn baby.
- must use effective contraception while you are being treated with YERVOY and for at least 3 months after the last dose of YERVOY if you are a woman who could become pregnant.
- are breast-feeding. YERVOY may pass into your breast milk. You and your doctor should decide if you will take YERVOY or breast-feed. You should not do both.

Always update your doctor or nurse on your medical conditions.

## INTERACTIONS WITH THIS MEDICATION

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines you obtained without a prescription. Do not start a new medicine before you talk to your doctor.

## PROPER USE OF THIS MEDICATION

YERVOY will be given to you in a hospital or clinic under the supervision of an experienced doctor.

YERVOY is a concentrate for solution for infusion. The amount of YERVOY you will be given will be calculated based on your body weight. Depending on your dose, some or all of the content of the YERVOY vial may be diluted with saline or glucose solution before use. More than one vial may be necessary to obtain the required dose.

When YERVOY is given on its own, it will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 90 minutes.

When YERVOY is given in combination with nivolumab, YERVOY is given as an infusion over 90 minutes (for the treatment of advance skin cancer) or 30 minutes (for the treatment of advanced kidney cancer). Nivolumab will be given on the same day (see section below for dosage and frequency of administration).

### **Dosage and frequency of administration:**

When YERVOY is given on its own, the recommended dose is 3 mg of ipilimumab per kilogram of your body weight. You will be treated with YERVOY once every 3 weeks for a total of 4 doses as tolerated, depending on your response to treatment.

When YERVOY is given in combination with nivolumab for the treatment of advance skin cancer, the recommended dose is 3 mg of ipilimumab per kilogram of your body weight once every three weeks for a total of 4 doses.

When YERVOY is given in combination with nivolumab for the treatment of advanced kidney cancer, the recommended dose is 1 mg of ipilimumab per kilogram of your body weight once every three weeks for a total of 4 doses.

### **Missed Dose:**

It is very important for you to keep all appointments to receive YERVOY. If you miss an appointment, ask your doctor when to schedule your next dose.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

YERVOY can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

The most common side effects with YERVOY are loss of appetite, diarrhea, feeling sick (nausea) or being sick (vomiting), stomach pain, itching, skin rash, and feeling tired or weak.

YERVOY acts on your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and may be life-threatening. Tears or holes (perforation) in the intestines, liver failure, severe skin reaction (toxic epidermal necrolysis), and paralysis (Guillain-Barré syndrome) have been reported.

**It is important to tell your doctor immediately if you have any of the symptoms listed in the table below or your symptoms get worse.** Your doctor can then give you treatment to prevent more severe complications. Your doctor may give you other medicines in order to reduce your symptoms, delay the next dose of YERVOY, or stop your treatment with YERVOY altogether. **Do not try to treat or diagnose symptoms yourself.** These symptoms are sometimes delayed, and may develop weeks or months after your last dose. Before treatment, your doctor will check your general health. You will also have blood tests before and during treatment.

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
<b>Common</b> (less than 1 in 10 but more than 1 in 100)	<b>Inflammation of the intestines (colitis)</b> <i>Symptoms may include:</i> <ul style="list-style-type: none"> <li>diarrhea (loose stools) or more bowel movements than usual. Do not treat the diarrhea yourself.</li> <li>constipation</li> <li>blood in stools or dark, tarry, sticky stools</li> <li>stomach pain (abdominal pain) or tenderness</li> </ul>		√	
<b>Common</b> (less than 1 in 10 but more than 1 in 100)	<b>Inflammation of the liver (hepatitis)</b> <i>Symptoms may include:</i> <ul style="list-style-type: none"> <li>yellowing of your skin or the whites of your eyes,</li> <li>dark urine, tiredness, nausea or vomiting, loss of appetite, pain on the right side of your stomach, or bruise easily</li> </ul>		√	
<b>Common</b> (less than 1 in 10 but more than 1 in 100)	<b>Inflammation of the skin</b> <i>Symptoms may include:</i> <ul style="list-style-type: none"> <li>rash on your skin, mouth blisters, or peeling skin</li> </ul>		√	
<b>Uncommon</b> (less than 1 in 100 but more than 1 in 1000)	<b>Inflammation of the nerves</b> <i>Symptoms may include:</i> <ul style="list-style-type: none"> <li>weakness of legs, arms or face</li> <li>numbness or tingling in hands or feet</li> </ul>		√	
<b>Common</b> (less than 1 in 10 but more than 1 in 100)	<b>Inflammation of certain glands (pituitary, adrenal glands, or thyroid) so they do not make enough hormone</b> <i>Symptoms may include:</i> <ul style="list-style-type: none"> <li>headaches or unusual tiredness or sleepiness</li> <li>changes in behavior such as less sex drive, being irritable or forgetful</li> <li>dizziness or fainting</li> </ul>		√	
<b>Uncommon</b> (less than 1 in 100 but more than 1 in 1000)	<b>Inflammation in other parts of the body including eyes, kidneys, pancreas, or lung</b> <i>Symptoms may include:</i> <ul style="list-style-type: none"> <li>blurry vision, double vision, or other vision problems</li> <li>eye pain or redness</li> </ul>		√	
<b>Uncommon</b> (less than 1 in 100 but more than 1 in 1000)	<b>Infusion reaction</b> <i>Symptoms may include:</i> <ul style="list-style-type: none"> <li>shortness of breath or trouble breathing, cough, chest tightness</li> <li>dizziness, fainting, rapid or weak heartbeat</li> <li>itching, hives, or feeling warm</li> <li>swelling of the throat, tongue, or face</li> <li>hoarse voice, throat tightness or trouble swallowing</li> </ul>		√	

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very rare (less than 1 in 10,000)	<p><i>Immune Disease (Vogt-Koyanagi-Harada Syndrome)</i></p> <p><i>Symptoms may include blurry vision, intolerance of bright light or other eye symptoms in combination with:</i></p> <ul style="list-style-type: none"> <li>• neck stiffness, headache</li> <li>• ear ringing, difficulty hearing, dizziness,</li> <li>• flu-like discomfort</li> <li>• skin discoloration, hair loss</li> </ul>		√	

Graft-versus-host disease, a complication that can happen after receiving a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic), may be severe, and can lead to death, if you receive YERVOY either before or after transplant. Your healthcare provider will monitor you for the following signs and symptoms: skin rash, liver inflammation, stomach-area (abdominal) pain, and diarrhea.

If you are having a stem cell transplant, tell your transplant doctor that you have received YERVOY in the past.

**Other side effects that have been reported (frequency not known) with YERVOY alone and/or YERVOY in combination with nivolumab include:**

- A condition where the immune system makes too many infection fighting cells called histiocytes and lymphocytes that may cause various symptoms (haemophagocytic lymphohistiocytosis)

*This is not a complete list of side effects. If you have any unexpected effects while taking YERVOY, contact your doctor or pharmacist.*

**HOW TO STORE IT**

It is unlikely that you will be asked to store YERVOY yourself. It will be stored in the hospital or clinic where it is given to you.

Keep out of the reach and sight of children.

Do not use YERVOY after the expiry date which is stated on the label and carton after EXP.

Store in a refrigerator (2°C – 8°C). Do not freeze.  
Store in the original package in order to protect from light.

Do not shake product.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 1908C  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at:  
<http://www.bmscanada.ca>  
or by contacting the sponsor, Bristol-Myers Squibb Canada at: 1-866-463-6267.

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