PART III: CONSUMER INFORMATION

PrILARIS®
(canakinumab)
*Pronounced ill**ARR**iss* (canakinumab)

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

ABOUT THIS MEDICATION

ILARIS treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of Periodic Fever Syndromes (CAPS, TRAPS, HIDS/MKD, FMF) & / or SJIA and familiar with ILARIS.

What the medication is used for:

Cryopyrin-Associated Periodic Syndrome (CAPS)

ILARIS is used in adults and children aged 2 years and older for the ongoing management of the following auto-inflammatory diseases which are collectively known as Cryopyrin-Associated Periodic Syndromes (CAPS), including:

- Familial Cold Autoinflammatory Syndrome (FCAS) also called Familial Cold Urticaria (FCU), presenting with signs and symptoms of cold-induced urticarial rash
- Muckle-Wells Syndrome (MWS)

ILARIS may also be used in Neonatal-Onset Multisystem Inflammatory Disease (NOMID)/ Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA). It is not known if ILARIS improves nervous system problems in patients with NOMID, such as inflammatory meningitis, hearing loss or pressure on the brain.

Tumor Necrosis Factor receptor Associated Periodic Syndrome (TRAPS)

ILARIS is used to treat Tumor Necrosis Factor (TNF) receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients.

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

ILARIS is used to treat Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients.

Familial Mediterranean Fever (FMF)

ILARIS is used to treat Familial Mediterranean Fever (FMF) in adult and pediatric patients. ILARIS can be used alone or together with colchicine.

ILARIS is also used for the treatment of:

Systemic Juvenile Idiopathic Arthritis (SJIA)

ILARIS is used to treat patients aged 2 years and older with active Systemic Juvenile Idiopathic Arthritis (SJIA).

What it does:

CAPS, TRAPS, HIDS/MKD and FMF
In patients with CAPS, TRAPS, HIDS/MKD and FMF, the body produces excessive amounts of a chemical messenger called interleukin-1 beta (IL-1 beta). This may lead to symptoms such as fever, headache, fatigue, skin rash, painful joints and muscles. In some patients, more severe outcomes such as hearing loss are observed.

SJIA
SJIA is an autoinflammatory disorder which can be caused by high levels of certain proteins in the blood such as interleukin-1 beta (IL-1 beta), and can cause fever, rash, headache, tiredness, or painful joints and muscles.

ILARIS belongs to a group of medicines called interleukin-1 (IL-1) inhibitors. The active substance in ILARIS is canakinumab, a human monoclonal antibody. It selectively binds to IL-1 beta, blocking its activity and leading to an improvement in symptoms.

When it should not be used:

You should not take ILARIS if you are allergic to canakinumab or to any nonmedicinal ingredients of ILARIS (see below for a list of nonmedicinal ingredients).

If you think you may be allergic to ILARIS solution, ask your doctor for advice. You may need a skin test before you start your treatment.

If you think you may have an infection, do not use ILARIS and ask your doctor for advice.

What the medicinal ingredient is:

canakinumab

What the important nonmedicinal ingredients are:

Powder for solution for injection: L-histidine, L-histidine HCl monohydrate, polysorbate 80, sucrose, water for injection (after reconstitution).

Solution for injection: L-histidine, L-histidine HCl monohydrate, mannitol, polysorbate 80, water for injection.

What dosage forms it comes in:

ILARIS is supplied as a powder for solution for injection. It is provided in a single-use vial. One vial of powder contains 150 mg canakinumab.

ILARIS is also supplied as a solution for injection. It is provided in a single-use vial. One vial of solution contains 150 mg/ 1 mL

canakinumab.

WARNINGS AND PRECAUTIONS

BEFORE using ILARIS talk to your doctor or pharmacist if:

- you currently have an infection or if you have a history of recurring infections or a condition such as low level of white blood cells, which makes you more likely to get infections.
- you require vaccinations. You must not be given a certain type of vaccination known as "live vaccines" while being treated with ILARIS.

DURING the treatment with ILARIS, tell your doctor immediately if you experience any of the following symptoms:

- Fever higher than 38°C/100°F, Fever lasting longer than 3 days or any other symptoms possibly related to an infection (including serious infection), such as prolonged cough, phlegm, chest pain, difficulty breathing, ear pain, prolonged headache or redness, warmth or swelling of your skin.
- Signs of an allergic reaction such as difficulty breathing or swallowing, nausea, dizziness, skin rash, itching, hives, palpitations (irregular heartbeat) or low blood pressure.
- Patients with SJIA may develop a serious condition called macrophage (a type of white blood cell) activation syndrome (MAS), which can cause death. Tell your doctor right away if your SJIA symptoms become worse, or if you have any symptoms of an infection such as fever, cough, or redness, warmth, or swelling of your skin.

CAPS, TRAPS, HIDS/MKD, FMF and SJIA: ILARIS is not recommended for children younger than 2 years of age.

INTERACTIONS WITH THIS MEDICATION

You must not be given a certain type of vaccination known as a "live vaccines" while being treated with ILARIS. Your doctor may want to check your vaccination history and give you any vaccinations that you have missed before you start treatment with ILARIS.

You should not take medicines that increase the risk of infection while taking ILARIS such as:

- Other blockers of interleukin-1, such as anakinra (Kineret*).
- Blockers of tumour necrosis factor (TNF), such as etanercept, (Enbrel*), adalimumab (Humira*) or infliximab (Remicade*) should not be used with ILARIS because this may increase the risk of infections. TNF blockers are used mainly in rheumatic and autoimmune diseases.

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins and herbal medicines.

PROPER USE OF THIS MEDICATION

Driving and using machines

Some symptoms associated with CAPS or with ILARIS treatment, such as a spinning sensation (known as vertigo), may affect your ability to drive or use machines. If you feel a spinning sensation, do not drive or operate any tools or machines until you are feeling normal again.

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Use in pregnancy and breast feeding.

ILARIS has not been studied in pregnant women. It is important to tell your doctor if you are pregnant or could be pregnant, or if you plan to get pregnant. Your doctor will discuss with you the potential risks of taking ILARIS during pregnancy. It is advised you avoid becoming pregnant, and that you use adequate birth control before starting ILARIS, while using ILARIS and for at least 3 months after the last ILARIS treatment.

If you received ILARIS while you were pregnant, it is important that you inform the baby's doctor or nurse before any vaccinations are given to your baby. Your baby should not receive live vaccines until at least 16 weeks after you received your last dose of ILARIS before giving birth.

It is not known if ILARIS is expressed in human breast milk, or what effects ILARIS could have on the baby. Breast-feeding is therefore not recommended in women who are being treated with ILARIS. It is important to tell your doctor if you are considering breast-feeding during or after treatment with ILARIS.

Use in children

ILARIS can be used in children aged 2 years of age and older.

Usual dose:

CAPS

The recommended starting dose of ILARIS for CAPS patients is:
Adults and children aged 2 years and above

- 150 mg for patients with body weight of more than 40 kg.
- 2 mg/kg for patients with body weight between 15 kg and 40 kg (example: a 25 kg child should receive a 50 mg injection).

Every 8 weeks a single dose of ILARIS is injected under the skin.

Do not exceed the recommended dose.

TRAPS, HIDS/MKD and FMF

The recommended starting dose of ILARIS for TRAPS, HIDS/MKD and FMF patients is:

- 150 mg for patients with body weight of more than 40 kg
- 2 mg/kg with body weight ≤40 kg.

With a starting dose of 150 mg or 2 mg/kg, if a satisfactory treatment response has not been achieved 7 days after treatment

start, a second dose of 150 mg or 2 mg/kg may be considered by your physician. If a full treatment response is then achieved, the higher dosing regimen of 300 mg or 4 mg/kg every 4 weeks should be maintained.

- Do not exceed the recommended dose.

SJIA

The recommended dose of ILARIS for SJIA patients 2 years and older is 4 mg/kg (up to a maximum of 300 mg).

ILARIS is injected every 4 weeks under the skin.

Do not exceed the dose.

Do not use more ILARIS than your doctor has recommended for you (see OVERDOSE below).

How to take ILARIS

After proper training in injection technique, you may inject ILARIS yourself.

- You and your doctor should decide together whether or not you will inject ILARIS yourself.
- Your doctor or nurse will show you how to inject yourself.
- Do not try to inject yourself if you have not been properly trained or if you are not sure how to do it.

Instructions for use of ILARIS

Please note that the preparation of the powder for solution for injection takes about 30 minutes.

The solution for injection requires no preparation.

Powder for solution for injection
Before beginning

- Find a clean, comfortable area.
- Wash your hands with soap and water.
- Check the expiry dates on the vial and syringes. Do not use if the expiry date has passed (last day of the month stamped on the vial).
- Always use new, unopened needles and syringes. Avoid touching the needles and the tops of the vials.

Read these instructions all the way through before beginning.

Gather together the necessary items
Included in the pack

A. one vial of ILARIS powder for solution for injection (keep refrigerated)

Not included in the pack

B. one vial of preservative-free sterile water for injection ("water") (do not refrigerate)

C. one 1mL syringe

D. one 18 G x 2" (50 mm) needle for reconstituting the powder ("transfer needle")

E. one 27 G x 0.5" (13 mm) needle for subcutaneous injection ("injection needle")

F. alcohol swabs

G. clean, dry cotton swabs

H. an adhesive bandage

I. a proper disposal container for used needles, syringe and vials (sharps container)

Mixing ILARIS

1. Remove the protective caps from the ILARIS (A) and water (B) vials. Do not touch the vial stoppers. Clean the stoppers with the alcohol swab (F).
2. Open the wrappers containing the syringe (C) and the transfer needle (D) (bigger one) and attach the needle to the syringe.
3. Carefully remove the cap from the transfer needle and set the cap aside. Pull the plunger all the way down to the 1.0 mL mark, filling the syringe with air. Insert the needle into the water vial through the centre of the rubber stopper (Fig. 1).

1

4. Gently push the plunger all the way down until air is injected into the vial.
5. Invert the vial and syringe assembly and bring to eye level (Fig. 2).

2

6. Make sure the tip of the transfer needle is covered by the water and slowly pull the syringe plunger down to slightly past the 1.0 mL mark. If you see bubbles in the syringe, remove bubbles as instructed by your healthcare provider or pharmacist.
7. Make sure 1.0 mL of water is in the syringe, then withdraw the needle from the vial. (There will be water remaining in the vial.)

8. Insert the transfer needle through the centre of the stopper of the vial of ILARIS powder, taking care not to touch the needle or the stopper. Slowly inject 1.0 mL of water in to the vial containing the ILARIS powder (Fig. 3).

3

9. Carefully remove the syringe with the transfer needle from the vial and recap the needle as instructed by your healthcare provider or pharmacist.

10. Without touching the rubber stopper, swirl (do not shake) the vial slowly at an angle of about 45 degrees for approximately 1 minute (Fig. 4a). Allow to stand for 5 minutes.

4a

11. Now, gently turn the vial upside down and back again ten times, again taking care not to touch the rubber stopper (Fig. 4b).

4b

12. Allow to stand for about 15 minutes at room temperature to obtain a clear to opalescent solution. Do not shake. Do not use if particles are present in the solution.
13. Make sure all of the solution is in the bottom of the vial. If drops remain on the stopper, tap the side of the vial to remove them. The solution should be clear to opalescent and free of visible particles. The solution should be colorless or may have a slight brownish-yellow tint.
14. If not used immediately after reconstitution, the solution should be stored in the refrigerator (2°C to 8°C) and used within 24 hours.

Preparing the injection

1. Clean the rubber stopper of the vial containing the ILARIS solution with a new alcohol swab.
2. Uncap the transfer needle again. Pull the plunger of the syringe all the way down to the 1.0 mL mark, filling the syringe with air. Insert the syringe needle into the vial of ILARIS solution through the centre of the rubber stopper (Fig. 5). Gently push the plunger all the way down until air is injected into the vial. Do not inject air into the medicine.

5

3. **Do not** invert the vial and syringe assembly (Fig. 6a). Insert the needle all the way into the vial until it reaches the bottom edge.

6a

4. Tip the vial to ensure that the required amount of solution can be drawn into the syringe (Fig. 6b). NOTE: The required amount depends on the dose to be administered. Your healthcare provider will instruct you on the right amount for you.

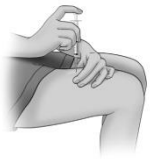
6b

5. Slowly pull the syringe plunger up to the correct mark, filling the syringe with ILARIS solution. If there are air bubbles in the syringe, remove bubbles as instructed by your healthcare provider. Ensure that the correct amount of solution is in the syringe.
6. Remove the syringe and needle from the vial. (There may be solution remaining in the vial.) Recap the transfer needle as instructed by your healthcare provider or pharmacist. Remove the transfer needle from the syringe. Place the transfer needle in the sharps container (I).
7. Open the wrapper containing the injection needle (E) and

attach this needle to the syringe. Set the syringe aside.

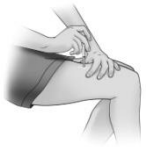
Giving the injection

1. Choose an injection site on the upper arm, upper thigh, abdomen or buttocks. Do not use an area that has a rash or broken skin, or is bruised or lumpy. Avoid injecting into scar-tissue as this may lead to insufficient exposure to canakinumab. Avoid injecting in to a vein.
2. Clean the injection site with a new alcohol swab. Allow the area to dry. Uncap the injection needle.
3. Gently pinch the skin up at the injection site. Hold the syringe at a 90-degree angle and in a single, smooth motion, push the needle straight down completely into the skin (Fig. 7).



7

4. Keep the needle all the way in the skin while slowly pushing the syringe plunger down until the barrel is empty (Fig. 8). Release the pinched skin and pull the needle straight out. Dispose of the needle and syringe in the sharps container without recapping or removing the needle.



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After the injection

5. Do not rub the injection area. If bleeding occurs, apply a clean, dry cotton swab over the area, and press gently for 1 to 2 minutes, or until bleeding stops (Fig. 9). Then apply an adhesive bandage (H).

9

6. Safely dispose of needles and syringe in the sharps container or as directed by your healthcare provider or pharmacist (Fig. 10). Never reuse syringes or needles.

10

7. Properly dispose of vials containing remaining water and ILARIS solution (if any) as directed by your healthcare provider or pharmacist. Any unused product or waste material should be disposed of in accordance with local requirements.

ILARIS 150 mg powder for solution for injection is for individual use only.

Never re-use left-over solution.

Keep the sharps container out of reach of children. Dispose of it as directed by your healthcare provider or pharmacist.

Solution for injection:

Before beginning

- Find a clean, comfortable area.
- Wash your hands with soap and water.
- After removing the vial from the refrigerator, check the expiry dates on the vial. Do not use if the expiry date has passed (last day of the month stamped on the vial).
- Let the vial stand unopened for 10 minutes to allow the contents to reach room temperature. Do not expose the vial to heat.
- Always use new, unopened needles and syringes. Avoid touching the needles and the top of the vial.

Read these instructions all the way through before beginning.

Gather together the necessary items

Included in the pack

A. one vial of ILARIS solution for injection (keep refrigerated)

Not included in the pack

B. one 1mL syringe

C. One appropriate size needle (e.g. 21G or larger) with appropriate length for withdrawing the solution ("withdrawal needle").

D. One 27 G x 0.5" needle for injecting ("injection needle").

E. alcohol swabs

F. clean, dry cotton swabs

G. an adhesive bandage

H. a proper disposal container for used needles, syringe and vials (sharps container)

Preparing the injection

1. Remove the protective cap from the vial (A). Do not touch the vial stopper. Clean the stopper with the alcohol swab (E).

2. Open the wrappers containing the syringe (B) and the withdrawal needle (C) (bigger one) and attach the needle to the syringe.

3. Carefully remove the cap from the withdrawal needle and set the cap aside. Insert the syringe needle into the vial of ILARIS solution through the centre of the rubber stopper (Fig. 1)

1

4. **Do not** invert the vial and syringe assembly. Insert the needle all the way into the vial until it reaches the bottom edge.

5. Tip the vial to ensure that the required amount of solution can be drawn into the syringe (Fig. 2).

2

6. Slowly pull the syringe plunger up to the correct mark, filling the syringe with ILARIS solution. If there are air bubbles in the syringe, remove bubbles as instructed by your healthcare provider. Ensure that the correct amount of solution is in the syringe.

NOTE: The required amount depends on the dose to be administered. Your healthcare provider will instruct you on the right amount for you.

7.Remove the needle and syringe from the vial and recap the withdrawal needle. Remove the withdrawal needle from the syringe and place in sharps container (H).

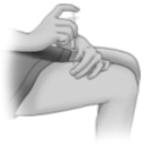
8.Open the wrapper containing the injection needle (D) and attach the needle to the syringe. Immediately proceed to administering the injection.

Giving the injection

1. Choose an injection site on the upper arm, upper thigh, abdomen or buttocks. Do not use an area that has a rash or broken skin, or is bruised or lumpy. Avoid injecting into scar-tissue as this may lead to insufficient exposure to canakinumab. Avoid injecting into a vein.

2. Clean the injection site with a new alcohol swab. Allow the area to dry. Uncap the injection needle.

3. Gently pinch the skin up at the injection site. Hold the syringe at a 90-degree angle and in a single, smooth motion, push the needle straight down completely into the skin (Fig. 3).



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4. Keep the needle all the way in the skin while slowly pushing the syringe plunger down until the barrel is empty (Fig. 4). Release the pinched skin and pull the needle straight out. Safely dispose of needles and syringe without recapping or removing the needle in the sharps container or as directed by your healthcare provider or pharmacist. Never reuse syringes or needles.

4

After the injection

5. Do not rub the injection area. If bleeding occurs, apply a clean, dry cotton swab over the area, and press gently for 1 to 2 minutes, or until bleeding stops. Then apply an adhesive bandage (G).

ILARIS 150 mg / 1 mL solution for injection is for individual use only.

Never re-use left-over solution.

Keep the sharps container out of reach of children. Dispose of it as directed by your healthcare provider or pharmacist.

How long to use ILARIS

You should continue using ILARIS for as long as your doctor tells you.

Overdose:

If you accidentally inject more ILARIS than the recommended dose, or sooner than you should, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you have CAPS, you should not inject ILARIS earlier than 8 weeks after the previous dose, unless your doctor tells you to. If you have TRAPS, HIDS/MKD or FMF, you should not inject ILARIS earlier than 4 weeks after the last dose, unless your doctor tells you to. If you accidentally inject more ILARIS or sooner than you should, inform your doctor, nurse or pharmacist, as soon as possible.

Missed Dose:
If you have forgotten to take a dose of ILARIS, inject the dose as soon as you remember then contact your doctor to discuss when you should take the next dose. You should then continue with injections at recommended intervals, or as recommended by your doctor.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients treated with ILARIS may experience side effects, although not everybody gets them. Most of the side effects are mild to moderate and will generally disappear a few days to a few weeks after treatment, but some side effects may be serious with medicines such as ILARIS and require your special attention to seek the care of your doctor.

Call your healthcare provider right away if you have any of these signs of an infection:

- a fever lasting longer than 3 days
- a cough that does not go away
- redness in one part of your body
- warm feeling or swelling of your skin
- sudden bleeding or easy bruising

Other possible side effects include:
Very common (affects more than 1 user in 10):

- sore throat with runny nose, blocked nose, sneezing, feeling of pressure or pain in the cheeks and/or forehead with or without fever (nasopharyngitis, pharyngitis, rhinitis)
- painful or frequent urination with or without fever (bladder or kidney infection)
- abdominal pain
- cold symptoms
- diarrhea
- stomach pain and feeling sick (gastroenteritis)
- flu (influenza)
- injection site reaction (such as redness, swelling, warmth, itching)
- headache

Common (affects 1 to 10 users in 100):

- nausea
- being sick (vomiting)
- abnormal levels of triglycerides in the blood (lipid metabolism disorder)
- feeling weak, fatigued (asthenia) or tired
- back pain
- combination of sore throat, fever, swollen or red tonsils, cough, difficulty to swallow and headache (tonsillitis)

Uncommon (affects 1 to 10 users in 1,000):

- heartburn (gastroesophageal reflux)

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 common	Fever lasting longer than 3 days or any other symptoms that might be due to an infection (for example, viral infection, bronchitis and ear infection) and serious infection (including chronic tonsillitis, lower respiratory tract infection, sepsis and other serious infections of the skin, lungs and blood). These include shivering, chills, malaise, loss of appetite, body aches, typically in connection with a sudden onset of illness, prolonged cough, phlegm, chest pain, difficulty breathing, ear pain, prolonged headache or localized redness, warmth or swelling of your skin or inflammation of connective tissues (cellulitis)			✓
	Sudden bleeding or easy bruising, which could be linked to low levels of blood platelets (thrombocytopenia)			✓
	Sore throat	✓		
Common	Feeling dizzy, spinning sensation (vertigo)	✓		

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	
	Fever, sore throat or mouth ulcers due to infections, which could be symptoms of low levels of white blood cells (leucopenia, neutropenia)			✓
	Increase in liver enzymes (transaminases) from a blood test		✓	
	Yellow skin and eyes, dark urine (signs of hepatitis; increase of bilirubin in CAPS patients)			✓
	Fever, cough, difficulty or painful breathing, wheezing, pain in chest when breathing (pneumonia)			✓
	Vaginal yeast infection	✓		
Not known	Trouble breathing or swallowing, nausea, dizziness, skin rash, itching, hives, palpitations (irregular heartbeat) or low blood pressure (signs of an allergic reaction)			✓
	Persistent cough, weight loss or low fever (signs of a tuberculosis infection)		✓	

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	
	Fever lasting longer than 3 days or any other symptoms that may be due to an infection, such as prolonged cough, phlegm, chest pain, blood in sputum, difficulty breathing, ear pain, prolonged headache or localized redness, warmth or swelling of your skin. (may be symptoms of a typical infection or one that may be more serious (opportunistic infections))			✓

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

HOW TO STORE IT

Keep out of the reach and sight of children.

Do not use ILARIS after the expiry date. The expiry date can be found on the label and carton. The expiry date refers to the last day of that month.

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

Store ILARIS preparation: if the reconstituted powder for solution for injection is not used immediately after preparation, it should be stored in the refrigerator (2°C to 8°C) and used within 24 hours, because it contains no preservative. If not used according to these recommendations, in-use storage times and conditions are the responsibility of the user.

Do not use ILARIS if you notice that the solution is not clear or contains particles. The solution should be clear and free of visible particles.

ILARIS is available as a single use vial. Any unused solution should be discarded.

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
- 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, ON 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.

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:
www.novartis.ca
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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Last revised: February 19, 2018

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