

## PART III: CONSUMER INFORMATION

### **Pr**BREO ELLIPTA fluticasone furoate/vilanterol dry powder for oral inhalation

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

#### **ABOUT THIS MEDICATION**

##### **What the medication is used for:**

**Chronic Obstructive Pulmonary Disease (COPD):**  
BREO ELLIPTA **100 mcg/25 mcg** is the **only** strength indicated for the treatment of COPD.

BREO ELLIPTA (**100 mcg/25 mcg**) is used:

- For the long-term treatment of chronic obstructive pulmonary disease (COPD).
- To reduce the likelihood of "flare-ups" in people with COPD who have previously had these events.

You will know you are having a "flare-up" if two of the following symptoms get worse for more than two days in a row:

- Unusual increase in the severity of breathlessness; cough, wheezing, or fatigue;
- Unusual colour, amount or thickness of mucus;
- Tightness in the chest or symptoms of a cold

##### **Asthma:**

BREO ELLIPTA **100 mcg/25 mcg and 200 mcg/25 mcg** are the strengths indicated for the treatment of asthma.

BREO ELLIPTA (**100 mcg/25 mcg and 200 mcg/25 mcg**) is used for the long term treatment of asthma in people aged 18 years and older:

- who have asthma that is not adequately controlled with a long term asthma medication such as an inhaled corticosteroid (ICS) alone; or
- whose asthma severity requires treatment with both an ICS and a long-acting beta<sub>2</sub> agonist (LABA).

##### **What it does:**

BREO ELLIPTA contains two active ingredients, fluticasone furoate and vilanterol.

- Fluticasone furoate is an ICS. It reduces inflammation in the airways of the lungs, which can ease breathing problems in COPD and asthma, and helps prevent "flare-ups" in COPD.

- Vilanterol is a LABA. It helps to open and relax the muscles in the airways. This allows more air to get in and out of the lungs and helps prevent shortness of breath and wheezing.

This medicine does not cure COPD or asthma but helps to control it.

##### **When it should not be used:**

Do not use BREO ELLIPTA:

- To treat sudden severe symptoms of COPD or asthma such as sudden shortness of breath or wheezing. **BREO ELLIPTA is not a rescue inhaler and should not be used to give you fast relief from your COPD or asthma attack.** You must use a rescue inhaler during a sudden COPD or asthma attack.
- If you are under 18 years of age;
- If you are allergic to any of the medicinal or nonmedicinal ingredients contained in the product;
- If you have a lactose or severe milk protein allergy.

##### **What the medicinal ingredients are:**

Fluticasone furoate and vilanterol.

##### **What the nonmedicinal ingredients are:**

Lactose monohydrate (which contains milk proteins) and magnesium stearate.

##### **What dosage forms it comes in:**

Dry Powder for Oral Inhalation: 100 mcg/25 mcg and 200 mcg/25 mcg.

The dry powder is contained in a series of separate blisters and is delivered by the ELLIPTA inhaler. Each dose contains 100 or 200 mcg of fluticasone furoate and 25 mcg of vilanterol.

Each inhaler contains 30 doses (one inhalation per day for 30 days).

If a sample is given to you by your doctor, it will contain 14 doses (one inhalation per day for 14 days).

## **WARNINGS AND PRECAUTIONS**

### **BEFORE you use BREO ELLIPTA, talk to your doctor or pharmacist if you:**

- Have liver disease, as you may be more likely to experience side effects;
- Have heart problems, irregular heart beat or high blood pressure;
- Are pregnant or planning to become pregnant;
- Are breastfeeding;
- Have ever had thrush or a yeast infection in your

mouth;

- Have ever had seizures;
- Have thyroid gland problems or disease;
- Have diabetes or high blood sugar;
- Have eye problems such as glaucoma, cataracts, blurry vision or other changes in vision;
- Have ever had to stop taking another medication for your breathing problems because you were allergic to it or it caused problems;
- Have been taking other corticosteroids by mouth or by inhalation;
- Have an immune system problem;
- Have any allergies to food or drugs;
- Have low levels of potassium in your blood;
- Have ever had herpes simplex of the eye, a history of tuberculosis infections, or any type of viral, bacterial, fungal (yeast), or parasitic infection.

#### Other warnings you should know about:

##### Asthma specific warnings:

- When LABA medicines are used alone without an ICS, they increase the risk of hospitalization and death from asthma problems. BREO ELLIPTA contains both an ICS and LABA. Studies showed that when an ICS and LABA are used together, there is not a significant increased risk in hospitalizations and death from asthma problems.
- Tell your doctor immediately if:
  - There is a change in your symptoms such as more coughing, attacks of wheezing, chest tightness, or an unusual increase in the severity of the breathlessness.
  - You wake up at night with chest tightness, wheezing or shortness of breath.
  - You are using increasing amounts of your fast acting ‘reliever’ medicine.

These could be warning signs that your condition may be worsening. Do not stop taking BREO ELLIPTA without talking to your doctor.

##### COPD specific warnings:

- Tell your doctor immediately if you notice symptoms of a “flare up”.
- Patients with COPD have a higher chance of getting pneumonia (a lung infection). Drugs like BREO ELLIPTA may also increase your chance of getting pneumonia. However, symptoms of pneumonia and COPD ‘flare ups’ frequently overlap. It is therefore important that you tell your doctor immediately if you suspect an infection as even mild chest infections should be treated immediately. Your doctor may also recommend that you receive a flu shot each year.

#### Warnings for the COPD and Asthma indications:

- **BREO ELLIPTA is not for the treatment of acute asthma attacks or sudden increase of breathlessness and wheezing in COPD.** If you get a sudden attack of wheezing and breathlessness between your doses of BREO ELLIPTA, you should use your fast acting ‘reliever’ medicine, such as salbutamol which your doctor has prescribed to you. Use the medication as directed by your doctor.
- If you no longer take an oral corticosteroid you should carry a warning card indicating that you may need supplementary corticosteroid treatment during periods of stress or a COPD flare-up.
- Do not use other medicines that contain a LABA for any reason. Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines.
- When using drugs like BREO ELLIPTA for long term treatment, you may be at risk of:
  - Breaking a bone (bone fractures);
  - Weak bones (osteoporosis; increased risk of bone fractures).

Take extra care to avoid any injury, especially falls.

- You should avoid coming into contact with people who have measles or chicken pox while taking BREO ELLIPTA. If you are exposed, tell your doctor right away.
  - Drugs like BREO ELLIPTA can cause eye disorders:
    - Cataracts: clouding of the lens in the eye, blurry vision, eye pain;
    - Glaucoma: an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss;
    - Central serous chorioretinopathy (CSCR): blurry vision or other changes in vision.
- Contact your healthcare professional if you experience blurry vision or other vision problems. You should have regular eye exams.
- **Pregnancy: BREO ELLIPTA is not usually recommended for use during pregnancy.** Before prescribing BREO ELLIPTA your doctor will consider the benefit to you and the risk to your unborn baby.
  - **Breastfeeding/ Lactation:** It is not known whether the ingredients of BREO ELLIPTA can pass into breast milk. If you are breast-feeding, **check with your doctor** before you take BREO ELLIPTA.

#### INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

Drugs that may interact with BREO ELLIPTA include:

- Ketoconazole used to treat fungal infections;
- Anti-HIV medicines (i.e. ritonavir, clarithromycin, indinavir, itraconazole, lopinavir, nelfinavir, saquinavir, voriconazole, atazanavir, cobicistat-containing products);
- Clarithromycin used to treat bacterial infections;
- Beta-blockers used to lower blood pressure (e.g. propranolol) or for other heart or eye problems (e.g. timolol);
- Medicines that decrease the level of potassium in your blood (i.e. diuretics). These are also known as “water pills” and are used to lower blood pressure;
- Medicines used in the treatment of depression (i.e. antidepressants, monoamine oxidase inhibitors).

### PROPER USE OF THIS MEDICATION

BREO ELLIPTA does not relieve sudden symptoms. Always have a rescue inhaler with you to treat sudden symptoms. If you do not have a rescue inhaler, call your healthcare provider to have one prescribed for you.

You should also try to avoid potential asthma triggers such as dust mites, mold, pets, tobacco smoke and pollen.

It is important that you continue to take BREO ELLIPTA regularly even if you feel fine and do not have any symptoms.

Do not stop taking BREO ELLIPTA without talking to your doctor.

Take BREO ELLIPTA:

- exactly as prescribed;
- every day;
- every 24 hours, at about the same time each day

Rinse your mouth with water after each inhalation. Do not swallow the water.

If you have any difficulties or you are unsure about how or when to take BREO ELLIPTA check with your doctor or pharmacist.

#### **COPD Usual Adult dose:**

One inhalation through the mouth once a day.

#### **Asthma Usual Adult dose:**

One inhalation through the mouth once a day.

- Your doctor will determine the dose based on the severity of your asthma and if you have liver disease.
- You should be re-evaluated by your doctor regularly to make sure you are taking the best dose for you.

- Your doctor will prescribe the lowest dose that works for your symptoms.

If you have liver disease, your doctor may decide that you should use the lower strength of BREO ELLIPTA (100mcg/25 mcg).

Do not take more than the recommended dose and do not change your dose unless your doctor has told you to.

#### **Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you accidentally take a larger dose of BREO ELLIPTA (i.e. more drug than recommended by your doctor), you may feel shaky, have a headache, or feel like your heart is beating faster than usual. Talk to your doctor or pharmacist right away if this occurs.

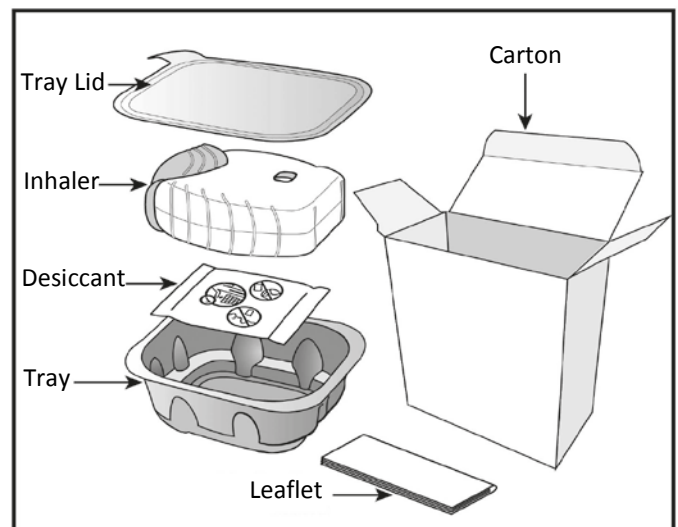
If you have taken larger doses than instructed for a long period of time, you should ask your doctor or pharmacist for advice.

#### **Missed Dose:**

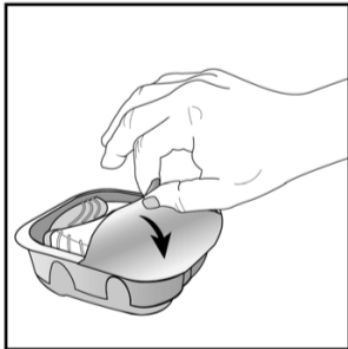
If you miss a dose, carry on and take your next dose at the usual time the next day. **Do not** take an extra dose to make up for the missed one.

#### **About your BREO ELLIPTA Inhaler:**

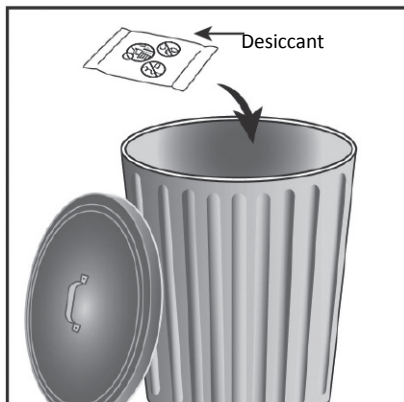
Your ELLIPTA inhaler carton contains:



The plastic ELLIPTA inhaler is packaged in a tray, with a peelable foil lid. **Do not remove the foil lid until you are ready to use the inhaler.** Peel back the lid to open the tray.



In the tray, you will find a small desiccant sachet containing a drying agent. The desiccant sachet helps to prevent moisture from forming inside the tray. **Keep it away from children and pets. Throw away the desiccant sachet** once you have opened the lid of the tray. It is dangerous to eat or inhale the contents of the desiccant sachet.



When you take your ELLIPTA inhaler out of its tray it will be in the closed position. Write the “Discard by” date on the inhaler label in the space provided. The “Discard by” date is 6 weeks from the date you open the tray.

The plastic ELLIPTA inhaler has a light grey body, a pale blue mouthpiece cover, and a dose counter. The mouthpiece and the air vent are hidden by the cover and can only be seen when the cover is opened. The ELLIPTA inhaler is ready-to-use. You will not need to prime it before using it for the first time.

**Cover**

Each time you open this, you prepare one dose of medicine.

**Dose Counter**

This shows how many doses of medicine are left in the inhaler.

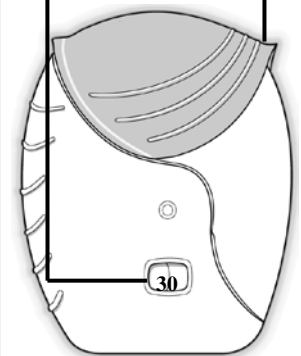
**Before the inhaler has been used, it shows exactly 30 doses (14 for sample and hospital packs).**

It counts down by 1 each time you open the cover.

**When fewer than 10 doses are left,** half of the dose counter shows red to remind you to refill your prescription.

**After you have inhaled the last dose,** half of the dose counter shows red and the number 0 is displayed. Your inhaler is now empty.

If you open the cover after this, the dose counter will change from half red to completely red.



**IMPORTANT:**

If you open and close the cover of the ELLIPTA inhaler without inhaling the medicine, you will lose a dose. The dose will be securely held inside the inhaler, but it will no longer be available. It is not possible to accidentally take extra medicine or take a double dose in one inhalation.

Never try to alter the numbers on the counter or detach the counter on the front of the ELLIPTA inhaler. The counter cannot be reset and is permanently attached to the inhaler.

**How to use BREO ELLIPTA:**

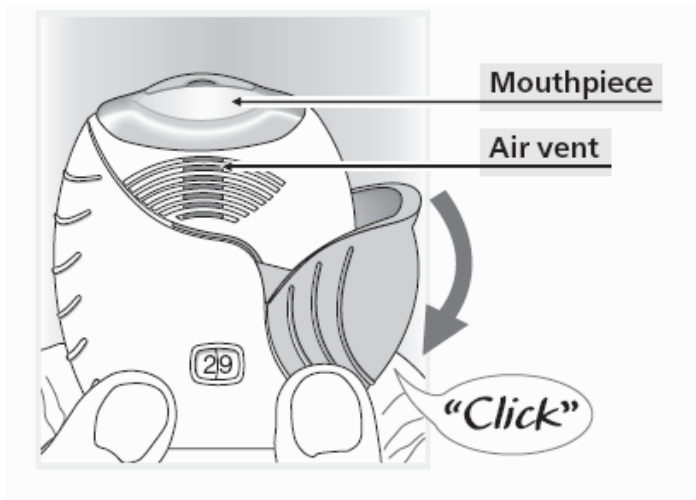
Please follow the instructions ‘**OPEN, INHALE, and CLOSE**’ to use your ELLIPTA inhaler. The instructions shown below apply to both the 30-dose and 14-dose ELLIPTA inhaler.

Keep the cover closed until you are ready to inhale a dose. Do not shake the ELLIPTA inhaler at any point during use as this is not necessary.

Sit down or stand in a comfortable position.

**OPEN:**

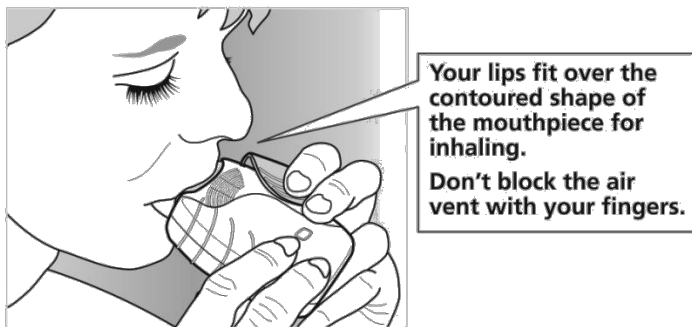
1. When you are ready, activate the inhaler by sliding the pale blue cover down until you hear a ‘click’ to prepare a dose.
2. The dose counter will now count down by one number (“1”). *It is unlikely the dose counter will not count down as you hear the ‘click’.* If this happens, it may mean the inhaler did not load the medicine. Bring it back to your pharmacist for advice.
3. While holding the inhaler away from your mouth, exhale a complete breath (i.e. breathe out as far as is comfortable). *Don’t breathe out into the inhaler.*



You are now ready to inhale a dose.

**INHALE:**

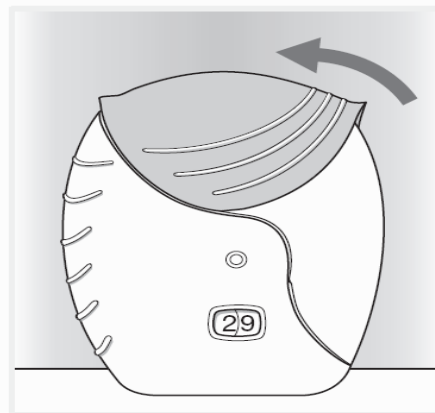
1. Put the mouthpiece between your lips, and close your lips firmly around it. *Don't block the air vent with your fingers.*



2. Take one long, steady, deep breath in. Hold this breath for as long as possible (minimum 3-4 seconds).

**CLOSE:**

1. Remove the inhaler from your mouth. Exhale slowly and gently. Continue to breathe normally.
2. You can clean the mouthpiece of the inhaler with a clean dry tissue after you have inhaled the medicine.
3. Close the inhaler by sliding the cover upwards as far as it will go to cover the mouthpiece.



You may not be able to taste or feel the medicine (this is normal), even when you are using the inhaler correctly.

4. Rinse your mouth with water. **Do not** swallow.



**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Side effects may include:

- Itchy, runny or blocked nose (nasopharyngitis)
- Infection of the nose or throat
- Common cold
- Sore, raised patches in the mouth or throat caused by a yeast infection (*candidiasis*/thrush). After using BREO ELLIPTA, rinse your mouth out with water immediately (do not swallow) as it may help stop this side effect from occurring. Cleaning dentures may also help
- Feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses called sinusitis)
- Pain and irritation in the back of the mouth and throat
- Headache
- Voice disorders
- Abdominal pain
- Flu (influenza)
- Back pain
- Cough
- Nausea
- High temperature (*fever*)
- Dizziness

- Painful joints
- Hoarseness and voice changes
- Respiratory tract infection
- Anxiety
- Tremor
- Muscle spasms

If any of these affects you severely, tell your doctor, nurse or pharmacist.

BREO ELLIPTA can cause abnormal blood test results such as decreased levels of potassium and increased blood sugar. Your doctor will decide when to perform blood tests and will interpret the results.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	<b>Thrush (yeast infection):</b> White patches in the mouth and on the tongue, sore throat		✓	
	<b>Bronchitis</b> (inflammation of the lungs).		✓	
	<b>Bone Fractures or Osteoporosis:</b> In situations where healthy people would not normally break a bone you may have sudden pain in any location and especially in the wrist, spine or hip. This may be a fracture.		✓	
	<b>COPD:</b> shortness of breath, cough, chest discomfort and coughing up mucus.		✓	
	High blood pressure, increased or irregular heart beat.		✓	
	<b>Pneumonia</b> (an infection of the lungs): Fever, chills, increase in sputum production, change in sputum colour, increased cough or an increase in breathing difficulties.		✓	

**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 seek immediate medical help
		Only if severe	In all cases	
	<b>Flu like symptoms</b> ( <i>influenza</i> ): sore throat, fever, headache, sore muscles, cough		✓	
Uncommon	<b>Decreased levels of potassium in the blood:</b> Irregular heartbeats, muscle weakness and spasms and generally feeling unwell		✓	
	<b>Increased blood sugar:</b> Frequent urination, increased thirst, hunger and unexplained tiredness	✓		

**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 seek immediate medical help
		Only if severe	In all cases	
Rare	<b>Paradoxical Bronchospasm</b> (worsening of symptoms related to breathing): Tightness of the chest associated with coughing, sudden worsening of shortness of breath and wheezing right after inhaling BREO ELLIPTA.			✓
	<b>Allergic Reaction:</b> Skin rash, hives, redness, swelling of the face, lips, tongue or throat (angioedema), becoming very wheezy, coughing or difficulty swallowing or breathing, suddenly feeling weak or light headed (may lead to collapse or loss of consciousness).			✓
	<b>Fast heartbeat</b>		✓	
	<b>Heart palpitations</b>		✓	
Very Rare	<b>Decreased Adrenal Function:</b> Tiredness, weakness, nausea and vomiting, low blood pressure.		✓	
Unknown	<b>Glaucoma:</b> New or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos or rainbows around items or red eyes		✓	

**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 seek immediate medical help
	Only if severe	In all cases	
<b>Cataract:</b> Clouding of the lens in the eye, blurry vision, and/or eye pain.		✓	
<b>Churg-Strauss Syndrome:</b> A flu-like illness, rash, pins and needles or numbness of arms and legs, severe sinusitis and worsening lung or breathing problems.		✓	

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

**HOW TO STORE IT**

- **Keep out of the reach and sight of children. Your medicine may harm them.**
- **Keep your inhaler in a cool dry place away from direct heat or sunlight.** Keep it closed when not in use.
- Do not store BREO ELLIPTA above 25°C. If you store in a refrigerator, **allow the inhaler to return to room temperature for at least an hour** before use.
- Store in the original package container in order to protect from moisture and do not open the foil lid until ready for first use.
- Once the tray is opened:
  - You can use the inhaler for up to 6 weeks, starting from the date you opened the lid of the tray.
  - Write the date the inhaler should be discarded on the inhaler in the space provided.
- Safely discard BREO ELLIPTA when the dose counter reads “0” or 6 weeks after you open the lid of the tray, whichever comes first. **BREO ELLIPTA expires 6 weeks after you have opened the lid of the tray.**

**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 <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- 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 <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

*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**

You may need to read this package insert again. **Please do not throw it away** until you have finished your medicine.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca> or by contacting the sponsor, GlaxoSmithKline Inc., at:  
7333 Mississauga Road  
Mississauga, Ontario  
L5N 6L4  
1-800-387-7374

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