PART III:
CONSUMER INFORMATION

BRICANYL®
TURBUHALER®
terbutaline sulfate powder for oral inhalation

Read this carefully before you start taking BRICANYL TURBUHALER and each time you get a refill. This leaflet is a summary and will not tell you everything about BRICANYL TURBUHALER. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about BRICANYL TURBUHALER.

ABOUT THIS MEDICATION

This medicine is prescribed for you by your doctor. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

What the medication is used for:
BRICANYL is a brand name for a drug called terbutaline, which belongs to the class of drugs referred to as bronchodilators. It is used to treat asthma, chronic bronchitis or other disorders which lead to breathing difficulties.

TURBUHALER is the brand name for a multiple dose, dry-powder inhaler. When you breathe in through the inhaler, your indrawn breath provides the necessary force to deliver the drug to your lungs.

What it does:
BRICANYL TURBUHALER is used to improve your breathing during times such as an asthma attack or when you feel a tightening of the airways. BRICANYL TURBUHALER widens your airways by relaxing the airway muscles, making it easier for you to breathe. It relieves symptoms such as wheezing, cough and shortness of breath and is effective even if you have an acute asthmatic attack.

The effect starts within a few minutes after you have inhaled the medicine and lasts for up to 7 hours.

When it should not be used:
You should not use BRICANYL TURBUHALER:
• if you are allergic to terbutaline sulfate;
• if you have a heart problem called tachyarrhythmia (fast and/or irregular heartbeat);
• for the treatment of preterm labour or miscarriage.

What the medicinal ingredient is:
terbutaline sulfate

What the nonmedicinal ingredients are:
BRICANYL TURBUHALER contains no other ingredients.

If you happen to shake the inhaler, the sound you hear is the drying agent built into the blue turning grip. This is not the medication and cannot be inhaled.

What dosage forms it comes in:
Powder for oral inhalation, containing 0.5 mg per inhalation (100 doses/Turbuhaler).

WARNINGS AND PRECAUTIONS

BEFORE you use BRICANYL TURBUHALER talk to your doctor or pharmacist:
• about all health problems you have now or have had in the past, including:
  o heart problems such as irregular heart beat, chest pain
  o high blood pressure
  o diabetes
  o disturbed thyroid function (hyperthyroidism)
  o a history of seizures;
• if you have ever had a bad, unusual or allergic reaction to terbutaline or to any other similar medicines;
• if you are over 65 years old;
• if you are pregnant, plan to become pregnant or are breastfeeding.
  o Pre-mature babies born to mothers who use BRICANYL TURBUHALER at the end of pregnancy may experience low blood sugar (hypoglycaemia). The symptoms may include jitteriness, poor body tone, poor feeding. Note that the symptoms of hypoglycaemia may resemble other conditions or medical problems. Always consult your baby’s physician for a diagnosis.

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 BRICANYL TURBUHALER include:
• Beta-blockers (some medicines for high blood pressure, heart conditions and some eye-drops) may reduce or block the effect of BRICANYL TURBUHALER
• Epinephrine (also known as adrenaline or adrenalin) for life threatening allergic reactions (anaphylactic reactions)
• Monoamine Oxidase Inhibitors for depression
• Tricyclic Antidepressants for depression
PROPER USE OF THIS MEDICATION

Dosage should be individualized.

Follow your doctor's directions carefully. They may differ from the information in this leaflet.

Usual dose:
Adults and children 6 years of age and older: one inhalation as required.

If required, a second dose may be taken. It is best to wait five minutes for the first dose to take effect before taking the second dose.

If symptoms persist after the second dose, you should immediately consult your doctor or the nearest hospital.

More than six inhalations (3.0 mg) should not be required in a 24 hour period.

You should see a doctor immediately if:
- your usual dose does not provide relief;
- your breathing condition gets worse;
- the effects of one dose last less than three hours;
- you are using BRICANYL TURBUHALER every day to relieve symptoms.

These may be signs that your asthma is getting worse. Your doctor may prescribe this medication in association with other anti-asthma medication that controls airway inflammation.

Do NOT exceed the dose prescribed by your doctor.

TURBUHALER is an inhaler from which very small amounts of powder are administered. When you breathe in through BRICANYL TURBUHALER the powder is delivered to the lungs. It is therefore important that you inhale as deeply and strongly as you can through the mouthpiece.

Because terbutaline sulfate is sensitive to moisture, avoid exhaling or breathing out into BRICANYL TURBUHALER.

A. Preparation before first use of a NEW (never been used) inhaler:
Before using your inhaler for the first time you need to prepare the inhaler for use. The preparation does not need to be repeated even if your inhaler is not used regularly.

STEP 1 Unscrew and lift off the cover. You may hear a rattling sound. This is normal; it is the sound of the drying agent, not the medication.

STEP 2 Holding the inhaler upright, turn the blue grip as far as it will go in one direction (clockwise or counter-clockwise, it does not matter which way you turn it first); then you must turn it back again as far as it will go in the opposite direction (Figure 1). Do not hold the mouthpiece when turning the grip. The click you hear is part of the loading process. Once you perform this step twice, the inhaler is ready to use.

B. Using the inhaler:
To use BRICANYL TURBUHALER properly, follow these 4 steps:

STEP 1 Unscrew and lift off the cover. You may hear a rattling sound. This is normal; it is the sound of the drying agent, not the medication.

STEP 2 Holding the inhaler upright, turn the blue grip as far as it will go in one direction (clockwise or counter-clockwise, it does not matter which way you turn it first); then you must turn it back again as far as it will go in the opposite direction (Figure 1). Do not hold the mouthpiece when turning the grip. The click you hear is part of the loading process. The inhaler is now ready to use.

If you do not hear the “click” sound when the turning grip is rotated, you will not receive any medication. If this problem persists, you need to replace the BRICANYL TURBUHALER. If you are not sure you heard the click, and you turn and click the inhaler a second time, you will not end up taking 2 doses by mistake. The design of the BRICANYL TURBUHALER makes it impossible to load more than one dose at a time, even if the inhaler is clicked several times.

STEP 3 Breathe out, with your mouth away from the mouthpiece. Then, place the mouthpiece gently between your teeth.

STEP 4 Now close your lips over the mouthpiece. Inhale as deeply and strongly as you can (Figure 2). Before you exhale, remember to remove the inhaler from your mouth. Repeat this process from Step 1 if more than one dose has been prescribed. Once you perform these steps, you have completed using..
BRICANYL TURBUHALER. Replace the cover and screw it shut.

You may not feel or taste the medication when inhaling. This is common.
Do not bite or chew the mouthpiece.
**Do not use BRICANYL TURBUHALER if it has been damaged or if the mouthpiece has become detached.**

Figure 1  Figure 2

With each inhalation some medication may stick to the inside of your mouth and throat. To reduce the risk of side effects it is advised that you, when possible, rinse your mouth with water after using BRICANYL TURBUHALER.

If you accidentally drop, shake or breathe out into BRICANYL TURBUHALER after it is loaded, you will lose your dose. If this happens, you should load a new dose and inhale it.

**Note:** Always replace the cover properly after use. Do not try to remove the mouthpiece or to twist it unnecessarily; it is fixed to the inhaler and must not be taken off.

**Cleaning:** Clean the outside of the mouthpiece once a week with a **dry** tissue. **Never** use water or any other fluid. If fluid enters the inhaler it may not work properly.

**When to start a new inhaler:** BRICANYL TURBUHALER has a dose indicator. When a red mark first appears in the little window underneath the mouthpiece, there are approximately 20 doses left. Now is the time to obtain your next inhaler.

When the red mark reaches the bottom of the window, BRICANYL TURBUHALER is **EMPTY**. If you shake the inhaler when it is empty, you will still be able to hear the sound of the drying agent. BRICANYL TURBUHALER cannot be re-filled with drug and should be discarded.

**Approximately 20 doses left**  **EMPTY**

**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.

**Missed dose:** BRICANYL TURBUHALER should be used as required rather than regularly. However, if you have been prescribed regular treatment and you forget to take a dose, take one as soon as you remember. If it is very close to the next dosing time, wait until then.

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

The most common side effects are nervousness and shakiness. These side effects disappear in most cases over the first few days of treatment.

Side effects may include:
- headache
- increased heart rate
- flushing, sweating, hives and rash
- occasional muscle cramps
- sleeplessness, drowsiness
- nervousness, restlessness, agitation, hyperactivity
- shakiness and tremors
- stomach upset, nausea, vomiting
- weakness, dizziness
- nausea and sweating

BRICANYL TURBUHALER can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.
SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

<table>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and seek emergency medical attention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Decreased levels of potassium in the blood: irregular heartbeats, muscle weakness and spasms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown Frequency</td>
<td>Fast or irregular heartbeats for an extended period of time</td>
<td>X</td>
</tr>
<tr>
<td>Paradoxical Bronchospasm: shortness of breath, chest tightness which causes wheezing immediately after inhaling your dose</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Myocardial Ischemia: chest pain related to heart problems and shortness of breath</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Allergic Reaction: swelling of the face, lips, tongue or throat, difficulty swallowing or breathing (or rash and hives in combination with the above)</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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

HOW TO STORE IT

Keep BRICANYL TURBUHALER out of the reach and sight of children.

Always replace and tighten the cover after using BRICANYL TURBUHALER. Store the inhaler at room temperature (15-30 °C) in a dry place, away from moisture.

Do not keep or use BRICANYL TURBUHALER after the expiry date indicated on the label.

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 0701E
    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.

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

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1 (800) 668-6000 Renseignements – 1 800 461-3787

This leaflet was prepared by: AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

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