

PART III: CONSUMER INFORMATION

FR BRICANYL[®] TURBUHALER[®]

terbutaline sulfate dry 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 for you. Only a doctor can prescribe it for you. 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 TURBUHALER is used to treat asthma, bronchitis and emphysema.

What it does:

BRICANYL TURBUHALER contains the medicine terbutaline. Terbutaline belongs to the class of drugs called bronchodilators. Bronchodilators relax the muscles in your airways. This helps to open your airways, making it easier for you to breathe. BRICANYL TURBUHALER relieves sudden symptoms such as wheezing, cough and shortness of breath.

BRICANYL TURBUHALER effect starts within 5 minutes after you have inhaled it and lasts for up to 7 hours.

When it should not be used:

Do not use BRICANYL TURBUHALER:

- if you are allergic to terbutaline sulfate;
- if you have a heart problem called tachyarrhythmia (fast and/or irregular heartbeat);
- to treat or prevent premature labour or miscarriage.

What the medicinal ingredient is:

Terbutaline sulfate.

What the nonmedicinal ingredients are:

BRICANYL TURBUHALER contains no other ingredients.

What dosage forms it comes in:

Dry powder for oral inhalation: 0.5 mg per dose. Each inhaler contains 100 doses.

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:
 - heart problems such as irregular heart beat, chest pain;
 - high blood pressure;
 - diabetes;
 - thyroid problems;
 - a history of seizures;
 - low levels of potassium in the blood;
- if you have ever had an 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.
 - 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 doctor for an opinion.

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, non-prescription medications, vitamins, minerals, natural supplements, or alternative medicines.

Drugs that may interact with BRICANYL TURBUHALER are:

- Beta-blockers (some medicines for high blood pressure, heart conditions and some eye-drops);
- Epinephrine (also known as adrenaline or adrenalin) for life threatening allergic reactions;
- Monoamine Oxidase Inhibitors for depression;
- Tricyclic Antidepressants for depression;
- Steroid medicines (such as prednisolone);
- Medicines called 'xanthines' (such as theophylline);
- Water pills (diuretics);
- If you are having surgery, tell the doctor (halothane medicines should be avoided).

PROPER USE OF THIS MEDICATION

The dosage of BRICANYL TURBUHALER is individual.

Follow your doctor's directions carefully. They may differ from the information in this leaflet. Check with your doctor or pharmacist if you are not sure.

Usual dose for Adults and children 6 years of age and older:

- one inhalation as needed.

- If needed, you may take a second dose. Wait five minutes for the first dose to take effect before taking the second dose.
- If your symptoms persist after the second dose, consult your doctor or the nearest hospital right away.
- You should not take more than six inhalations (3.0 mg) in a 24-hour period.

See a doctor right away 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.

Missed dose:

BRICANYL TURBUHALER should be used as needed 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.

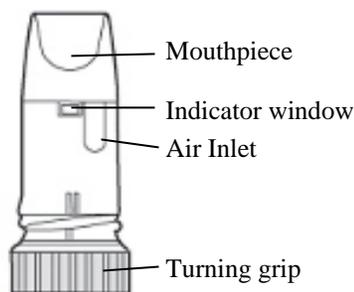
Overdose:

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.

HOW TO USE YOUR BRICANYL TURBUHALER INHALER

Before you start using BRICANYL TURBUHALER for the first time it is important that you read the instructions below and follow them carefully.

TURBUHALER is a multidose 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.



Before you use a **NEW** inhaler for the first time you must prepare the inhaler for use. Follow the steps under “**A. How to prepare a NEW inhaler for use:**”.

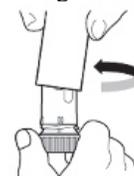
For usual use of your inhaler follow the steps under “**B. How to take a dose:**”.

A. How to prepare a NEW inhaler for use:

You only need to prepare your **NEW** inhaler for use **once**. You do not need to repeat these steps even if your inhaler is not used frequently.

STEP 1 Unscrew and lift off the cover (Figure 1).

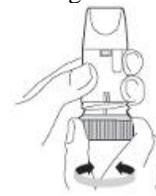
Figure 1



STEP 2 Hold the inhaler upright. Do not hold the inhaler by the mouthpiece.

- 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 turn the blue grip as far as it will go in the opposite direction (Figure 2).
- At some point when you are turning the grip you will hear a “**click**”. This is part of the preparation process.

Figure 2



STEP 3 **Repeat STEP 2** one more time. Then follow the steps under “**B. How to take a dose:**”, **starting at STEP 2.**

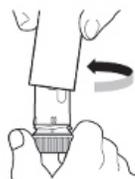
B. How to take a dose:

To properly take a dose, follow these 4 steps:

STEP 1 Unscrew and lift off the

Figure 1

cover (Figure 1).



STEP 2 Hold the inhaler upright. Do not hold the inhaler by the mouthpiece.

- 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 turn the blue grip as far as it will go in the opposite direction (Figure 2).



A dose has now been loaded.

- At some point when you are turning the blue grip, you will hear a “click”. This is part of the loading process.

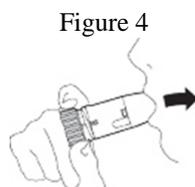
NOTE: If you accidentally **drop, shake** or **breathe out** into BRICANYL TURBUHALER after the dose has been loaded, you will lose your dose. If this happens, repeat STEP 2 to load a new dose.

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



STEP 4 Now close your lips over the mouthpiece. Do not bite or chew the mouthpiece.

- **Inhale as deeply and strongly** as you can (Figure 4).
- You may not feel or taste the medication when inhaling. This is common.
- Before you exhale, remember to remove the inhaler from your mouth.



been prescribed. When you have taken the prescribed amount of doses, **replace the cover of the inhaler by screwing it back on.** With each inhalation some medication may stick to the inside of your mouth and throat. To reduce the risk of side effects rinse your mouth with water, and do not swallow.

Note: Do not try to remove the mouthpiece or to twist it unnecessarily. It is fixed to the inhaler and must not be taken off.

I cannot remember how many times I turned the blue grip. What should I do?

The TURBUHALER is designed to load only one dose at a time. If you can't remember how many times you have turned the blue grip, you can start the process again. Follow the steps below. You will not end up loading two doses.

If you are using a **NEW** inhaler for the first time, start at the beginning of STEP 2 under the section “**A. How to prepare a NEW inhaler for use:**”.

For usual use of your inhaler, start at the beginning of STEP 2 under the section “**B. How to take a dose:**”.

How do I know my dose has been loaded?

By turning the blue grip all the way in BOTH directions, you will properly load a dose of your medication. At some point when you are turning the grip you will hear a “click”. This is part of the loading process. If you are not sure you heard the “click”, repeat from the beginning of STEP 2 under the section “**B. How to take a dose:**”. This will not result in two doses being loaded. The TURBUHALER is designed to load only one dose at a time. 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.

How do I clean my inhaler?

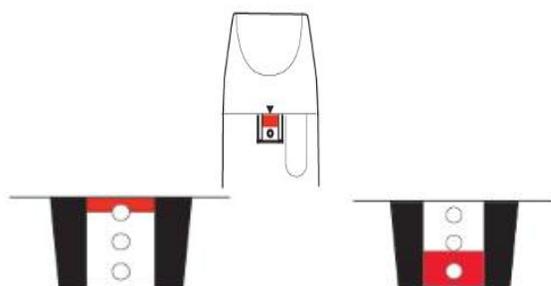
Clean the outside of the mouthpiece once a week with a **dry** tissue. **Never** use water or any other fluid. If fluid enters the inhaler it may not work properly.

How do I know 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 (Figure 5). Now is the time to obtain your next inhaler. When the red mark reaches the bottom of the window, you should discard your inhaler. The sound you hear if you shake the inhaler is produced by a drying agent, not the medication. BRICANYL TURBUHALER cannot be refilled with drug and should be thrown away.

Figure 5

Repeat STEPS 2-4 if more than one dose has



Approximately 20 doses left

EMPTY

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;
- flushing, sweating, hives and rash;
- occasional muscle cramps;
- sleeplessness, drowsiness;
- nervousness, restlessness, agitation, hyperactivity;
- shakiness;
- stomach upset, nausea, vomiting;
- weakness, dizziness;
- nausea and sweating.

BRICANYL TURBUHALER may affect blood sugar levels. If you are diabetic you may need to check your blood glucose more frequently. Your doctor will advise you about this.

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 emergency medical attention
		Only if severe	In all cases	
Rare	Low potassium levels in the blood: irregular heartbeats, muscle weakness and spasms		X	
Unknown Frequency	Fast or irregular heartbeats for an extended period of time		X	

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 emergency medical attention
	Only if severe	In all cases	
Paradoxical Bronchospasm: shortness of breath, chest tightness which causes wheezing immediately after inhaling your dose			X
Myocardial Ischemia: chest pain related to heart problems and shortness of breath		X	
Allergic Reaction: swelling of the face, lips, tongue or throat, difficulty swallowing or breathing (or rash and hives in combination with the above)			X

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).

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Call toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION 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: 1-800-668-6000.

This leaflet was prepared by:

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