

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

## **Pr**TUDORZA<sup>®</sup> GENUAIR<sup>®</sup> aclidinium bromide dry powder for oral inhalation

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

#### 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:

TUDORZA GENUAIR is used long term to help open the airways of adults with breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD).

#### What it does:

The active ingredient of TUDORZA GENUAIR is aclidinium bromide, which belongs to a group of medicines called bronchodilators. Bronchodilators help to open and relax the muscles of the airways. This allows more air to get in and out of the lungs. This makes it easier for patients with COPD to breathe and helps prevent shortness of breath and wheezing.

#### When it should not be used:

Do not use TUDORZA GENUAIR if you:

- are allergic to aclidinium bromide or any of the other ingredients of this medicine;
- are under 18 years of age;
- experience sudden severe symptoms of COPD (called a COPD flare-up), such as sudden shortness of breath or wheezing. Your doctor may give you other medicine to use for sudden breathing problems as needed.

#### What the medicinal ingredient is:

Aclidinium bromide.

#### What the nonmedicinal ingredients are:

Lactose monohydrate.

#### What dosage forms it comes in:

Dry powder for oral inhalation: 400 mcg aclidinium bromide. Your inhaler can contain either 30 or 60 metered doses.

#### WARNINGS AND PRECAUTIONS

**BEFORE you use TUDORZA GENUAIR talk to your doctor or pharmacist if you:**

- are pregnant or planning to become pregnant;
- are breastfeeding;
- are taking any medications including eye drops, this includes medications you can buy without prescription;
- have had heart problems recently;
- have eye problems such as glaucoma, eye pain, blurred vision, see halos around lights or coloured images;
- have an enlarged prostate, problems passing urine, or painful urination;
- have a severe allergy to milk proteins. Ask your doctor if you are not sure;
- have had allergies to atropine or related medicines, for example ipratropium, tiotropium or oxitropium;
- have allergies to food or drugs.

TUDORZA GENUAIR should not be used more frequently than twice daily. Do not exceed the prescribed dose.

Remember to tell any other doctor, dentist or pharmacist you consult that you are taking this medication.

Stop taking TUDORZA GENUAIR and seek medical help right away:

- if you get tightness of the chest, coughing, wheezing or breathlessness immediately after using the medicine. These may be signs of a condition called bronchospasm.

#### Driving and using machines:

Avoid driving and using machines if you have blurred vision or headaches.

## INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Tell your doctor if you have been or are using similar medicines for breathing problems, e.g. medicines containing tiotropium, ipratropium or glycopyrronium. Ask your doctor or pharmacist if you are not sure. The use of TUDORZA GENUAIR with these medicines is not recommended.

## PROPER USE OF THIS MEDICATION

Always use TUDORZA GENUAIR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is one inhalation twice a day, once in the morning and once in the evening;
- Use TUDORZA GENUAIR even when you have no breathing problems or other symptoms of COPD;
- Do not stop using the drug without consulting your doctor;
- You can use TUDORZA GENUAIR anytime before or after food or drink.

### Usual adult dose:

The recommended dose is one inhalation twice a day, once in the morning and once in the evening.

The recommended dose can be used for elderly patients and for patients with kidney or liver problems. No dose adjustments are necessary.

### Overdose:

If you think you may have used more TUDORZA GENUAIR than you should, contact your doctor or pharmacist.

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:

If you forget a dose of TUDORZA GENUAIR, inhale the dose as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

## Instructions for Use

**Before using the TUDORZA GENUAIR inhaler, read the full Instructions for Use. It is important that you read this information as the GENUAIR may work differently from inhalers you have used. If you have any questions ask your doctor or pharmacist.**

The Instructions for Use is divided into the following sections:

- Getting started
- Step 1: Prepare your dose
- Step 2: Inhale your medicine
- Additional information

## Getting Started

TUDORZA GENUAIR is a multidose dry powder inhaler that uses your breath to deliver the medicine directly into your lungs. It is important that you become familiar with the parts of your GENUAIR inhaler (Figure A).

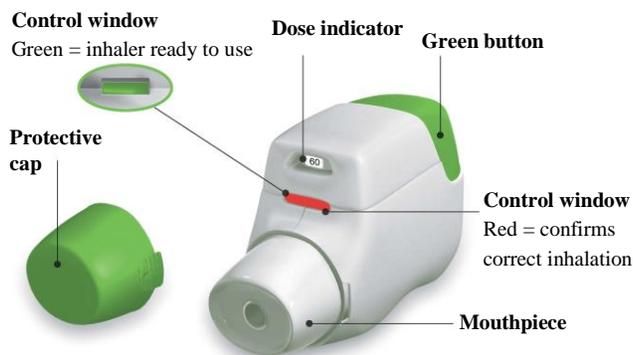
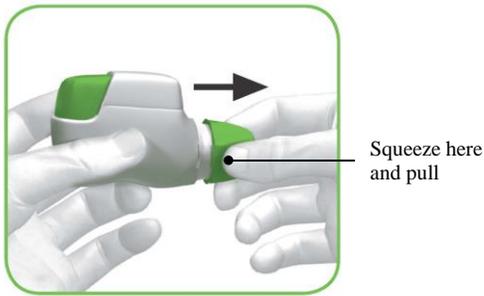


Figure A

## Before use:

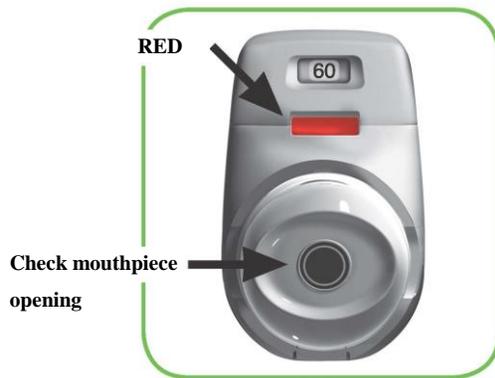
- a) Before first use, tear open the sealed bag and remove the inhaler. Throw away the bag.
- b) **Do not** press the green button.
- c) Pull off the protective cap by lightly squeezing the arrows marked on each side (Figure B).



**Figure B**

**STEP 1: Prepare your dose**

- 1.1 Look in the opening of the mouthpiece and make sure nothing is blocking it (Figure C).
- 1.2 Look at the control window. It should be red (Figure C).



**Figure C**

- 1.3 Hold the inhaler horizontally with the mouthpiece facing you and the green button on top (Figure D).



**Figure D**

- 1.4 Press the green button all the way down to load your dose (Figure E).

When you press the button all the way down, the control window changes from red to green.

Make sure the green button is on top. **Do not tilt the inhaler.**

- 1.5 Release the green button (Figure F).

Make sure you release the button so the inhaler can work correctly.



**Figure E**



**Figure F**

**Stop and Check:**

- 1.6 Make sure the control window is now green (Figure G). Your medicine is ready to be inhaled.

Go to 'STEP 2: Inhale your medicine'.



**Figure G**

What to do if the control window is still red after pressing the button (Figure H).



Figure H

The dose is not prepared. Go back to 'STEP 1: Prepare your dose' and repeat steps 1.1 to 1.6.

### STEP 2: Inhale your medicine

Read steps 2.1 to 2.7 fully before taking your dose. Do not tilt the inhaler.

2.1 Hold the inhaler away from your mouth, and **breathe out completely** (Figure I). Never breathe out into the inhaler.

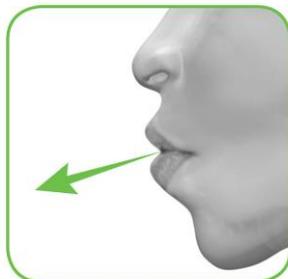


Figure I

2.2 Hold your head upright, put the mouthpiece between your lips, and close your lips tightly around it.

**Do not hold the green button down while inhaling.**

2.3 Take a **strong, deep breath** through your mouth. Keep breathing in for as long as possible (Figure J).

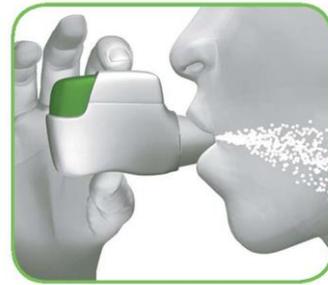


Figure J

A 'click' will let you know that you are inhaling correctly. **Keep breathing in as long as possible after you hear the 'click'**. If you do not hear the 'click', continue with Steps 2.4-2.7 and use the control window to ensure you have inhaled correctly.

2.4 Take the inhaler out of your mouth.

2.5 Hold your breath for as long as possible.

2.6 Slowly breathe out away from the inhaler.

Some patients may experience a grainy sensation in their mouth, or a slightly sweet or bitter taste. Do not take an extra dose even if you do not taste or feel anything after inhaling.

### Stop and Check:

2.7 Make sure the control window is now red (Figure K). This means you have inhaled your medicine correctly.



Figure K

**What to do if the control window is still green after inhalation (Figure L).**



**Figure L**

This means you have not inhaled your medicine correctly. **Go back to ‘STEP 2: Inhale your medicine’ and repeat steps 2.1 to 2.7.**

If the control window still does not change to red, you may have forgotten to release the green button before inhaling, or you may not have inhaled strongly enough. If this happens, try again. Make sure you have released the green button, and then go back to ‘STEP 2: Inhale your medicine’ and repeat steps 2.1 to 2.7. Make sure that you have breathed out completely before you take a strong, deep breath through the mouthpiece.

**Please contact your doctor or pharmacist if the control window is still green after repeated attempts.**

Push the protective cap back onto the mouthpiece after each use (Figure M). This prevents contamination of the inhaler with dust or other materials. You should discard your inhaler if you lose the protective cap.



**Figure M**

### Additional information

**What should you do if you accidentally prepare a dose?**

Do not tilt your inhaler. Store it with the protective cap in place until it is time to inhale your medicine, then remove the protective cap and start at Step 1.6.

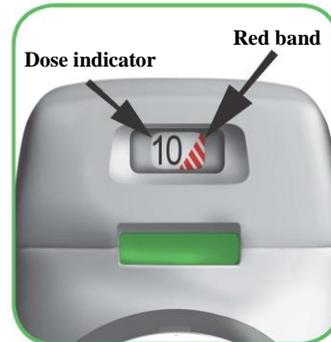
**How does the dose indicator work?**

The dose indicator shows the total number of doses left in the inhaler (Figure N).

On first use, every inhaler contains at least 60 doses, or at least 30 doses, depending on the pack size.

Each time you load a dose by pressing the green button, the dose indicator moves by a small amount towards the next number (50, 40, 30, 20, 10, or 0).

**Dose indicator moves slowly from 60 to 0: 60, 50, 40, 30, 20, 10, 0.**



**Figure N**

**When should you get a new inhaler?**

You should get a new inhaler:

- If your inhaler appears to be damaged or if you lose the protective cap, or
- When a **red band** appears in the dose indicator, this means you are nearing your last dose (Figure N), or
- If your inhaler is empty (Figure O).



**Figure O**

**How do you know that your inhaler is empty?**

When the green button will not return to its full upper position and is locked in a middle position, you have reached the last dose (Figure O). Even though the green button is locked, your last dose may still be inhaled. After that, the inhaler cannot be used again and you should start using a new inhaler.

**How should you clean the inhaler?**

NEVER use water to clean the inhaler, as this may damage your medicine. If you wish to clean your inhaler, just wipe the outside of the mouthpiece with a dry tissue or paper towel.

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

Like all medicines, TUDORZA GENUAIR can cause side effects, although not everybody gets them.

Side effects may include:

- headache;
- nasopharyngitis (inflammation or irritation of the nose and throat);
- cough;
- falls and injury;
- sinus inflammation (sinusitis);
- blurred vision;
- hoarseness (dysphonia);
- dizziness;
- mouth or tooth infection;
- thrush in the mouth or throat;
- inflammation of the mouth (stomatitis);
- pain, stiffness and swelling in the joints;
- rash, skin itching.

<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	
<b>Common</b>			
Nausea and/or diarrhea	√		
<b>Uncommon</b>			
Dry mouth	√		
<b>Heart failure:</b> Fatigue; shortness of breath; or swelling of ankles or legs		√	

<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	
<b>Hyperglycemia:</b> High level of blood sugar (typical symptoms include excessive thirst or hunger and frequent urination)		√	
Vomiting and/or abdominal pain	√		
Faster heart beat		√	
Difficulty and pain passing urine or a feeling that your bladder has not completely emptied (urinary retention)		√	
<b>Rare</b>			
<b>Glaucoma:</b> New or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos of bright colours around lights, red eyes			√
<b>Unknown</b>			
<b>Paradoxical Bronchospasm:</b> Tightness of the chest associated with coughing, wheezing, or breathlessness immediately after inhalation of TUDORZA GENUAIR			√
<b>Serious allergic reactions:</b> rash, hives, swelling of the face, mouth, lips and tongue with or without breathing problems			√
Difficulty breathing		√	

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

**HOW TO STORE IT**

Keep TUDORZA GENUAIR out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the inhaler label and carton after “EXP”. The expiry date refers to the last day of the month.

Store between 15 to 30°C.

Keep the TUDORZA GENUAIR inhaler protected inside the sealed bag until you start to use it. Use the TUDORZA GENUAIR inhaler within 90 days of opening the bag.

Do not use the TUDORZA GENUAIR if you notice that the pack is damaged or shows signs of tampering.

After you have taken the last dose, the inhaler has to be disposed of. You should follow local guidelines for domestic waste when throwing away the empty or unused inhaler. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

This leaflet was prepared by:  
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### **REPORTING 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 most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: [www.astrazeneca.ca](http://www.astrazeneca.ca) or by contacting the sponsor, AstraZeneca Canada Inc. at: 1-800-668-6000.