

**PART III:
CONSUMER INFORMATION**

DUAKLIR® GENUAIR®
aclidinium bromide/formoterol fumarate dihydrate
dry powder for oral inhalation

This leaflet is part III of a three-part "Product Monograph" published when DUAKLIR 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 DUAKLIR 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:

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

DUAKLIR GENUAIR is **NOT** for treating asthma or sudden, severe symptoms of COPD.

If you are a smoker, it is important to quit smoking. This will help decrease the symptoms of COPD and potentially increase your lifespan.

What it does:

DUAKLIR GENUAIR contains two active ingredients:

- Acclidinium bromide is a long-acting muscarinic antagonist (LAMA).
- Formoterol fumarate dihydrate is a long-acting beta₂-agonist (LABA).

Both belong 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.

This medicine does not cure COPD but helps to control it. It is important that you take DUAKLIR GENUAIR regularly even if you feel fine.

When it should not be used:

Do not use DUAKLIR GENUAIR:

- if you are allergic to acclidinium bromide, formoterol fumarate or any of the other ingredients of this medicine;
- if you are under 18 years of age;
- to treat sudden severe symptoms of COPD (called a COPD flare-up), such as sudden shortness of breath or wheezing. If you experience this sort of attack you must use a rapid onset, short duration, inhaled bronchodilator such as salbutamol (rescue medication). Keep this rescue medication with you at all times;
- to treat asthma.

What the medicinal ingredients are:

acclidinium bromide and formoterol fumarate dihydrate

What the nonmedicinal ingredients are:

lactose monohydrate

What dosage forms it comes in:

Dry powder for oral inhalation: 400 mcg of acclidinium bromide and 12 mcg of formoterol fumarate dihydrate. Your inhaler will contain 60 metered doses.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
DUAKLIR GENUAIR should only be used to treat COPD.
DUAKLIR GENUAIR should not be used to treat asthma.

You are advised that in patients with asthma, long-acting beta₂-agonist (LABA) medicines may increase the chance of death from asthma problems. In a large asthma study, more patients who used another LABA medicine (salmeterol) died from asthma problems compared with patients who did not use that LABA medicine. This finding may also apply to DUAKLIR GENUAIR.

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

- have heart problems, such as rapid or irregular heart beat or an abnormal electrical signal called "prolongation of the QT interval";
- have high blood pressure;
- have diabetes;
- have low levels of potassium in your blood;
- have seizures;

- have thyroid gland problems or disease;
- have a tumour in one of your adrenal glands (phaeochromocytoma);
- are taking similar medicines for your lung disease;
- are pregnant or planning to become pregnant;
- are breastfeeding. It is not known if DUA KLIR GENUAIR can pass into breastmilk;
- are taking any medications including eye drops, this includes medications you can buy without prescription;
- 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 allergies to food or drugs.

DUA KLIR 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.

During treatment with DUA KLIR GENUAIR, tell your doctor right away if you experience any of the following symptoms:

- **stop taking DUA KLIR GENUAIR and tell your doctor immediately** if you experience a tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation of DUA KLIR GENUAIR (signs of bronchospasm);
- **stop taking DUA KLIR GENUAIR and tell your doctor immediately** if you experience difficulties in breathing or swallowing, swelling of tongue, lips and face, hives or itching, skin rash (signs of hypersensitivity reaction). Do not use DUA KLIR GENUAIR again before speaking with your doctor;
- **stop taking DUA KLIR GENUAIR and tell your doctor immediately** if you experience eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes; these may be signs of an acute attack of narrow-angle glaucoma;
- if your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they worsen during your treatment.

DUA KLIR GENUAIR does not relieve sudden symptoms of COPD. Always have a short-acting

bronchodilator medicine with you to treat acute symptoms. If you do not have an inhaled, short-acting bronchodilator, ask your doctor to have one prescribed for you.

Get emergency medical care if:

- breathing problems worsen quickly;
- you use your short-acting bronchodilator medicine, but it does not relieve your breathing problems.

Driving and using machines:

Avoid driving and using machines if you feel dizzy, 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.

Drugs that may interact with DUA KLIR GENUAIR include:

- Any medicines that may be similar to DUA KLIR GENUAIR (contain the same or similar active ingredients, e.g. medicines containing acclidinium, tiotropium, ipratropium glycopyrronium, formoterol or salmeterol);
- Oral corticosteroids (prednisone);
- Diuretics (water pills);
- Xanthine medicines (such as theophylline) used to treat asthma;
- Beta blocker medicines used to treat high blood pressure or other heart problems (such as atenolol or propranolol) or to treat glaucoma (such as timolol eye drops);
- Medications used to treat depression or sad mood (monoamine oxidase inhibitors and tricyclic antidepressants);
- Macrolide antibiotics (such as erythromycin, azithromycin, clarithromycin);
- Antihistamines;
- Inhaled anaesthetics such as halogenated hydrocarbons (e.g. halothane), used during surgery. Inform your doctor that you use DUA KLIR GENUAIR if you are to have surgery under anaesthesia.

Other Drugs: Drugs such as quinidine, disopyramide, procainamide, phenothiazines, antihistamines, and tricyclic antidepressants may be associated with QT-interval prolongation and an

increased risk of heart problems (see WARNINGS AND PRECAUTIONS).

PROPER USE OF THIS MEDICATION

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

- Use DUAKLIR GENUAIR even when you have no breathing problems or other symptoms of COPD.
- Do not use DUAKLIR GENUAIR more than twice a day or at higher doses than recommended by your doctor.
- Do not stop using the drug without consulting your doctor.
- You can use DUAKLIR 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.

Overdose:

If you think you have taken too much DUAKLIR GENUAIR, 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 DUAKLIR 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 DUAKLIR 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

DUAKLIR GENUAIR is a multidose 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).

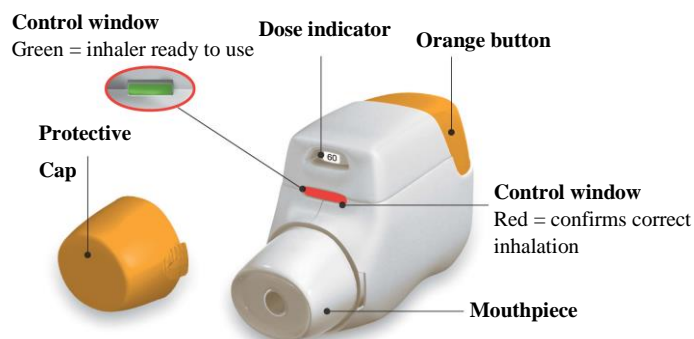


Figure A

Before use:

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

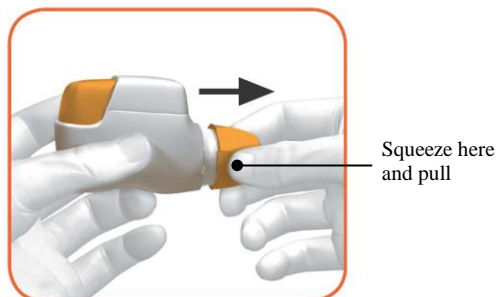


Figure B

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).

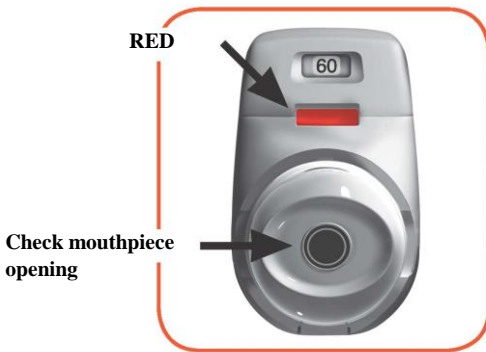


Figure C

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



Figure D

1.4 Press the orange 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 orange button is on top. **Do not tilt the inhaler.**

1.5 Release the orange 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 orange 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 orange button before inhaling, or you may not have inhaled strongly enough. If this happens, try again. Make sure you have released the orange 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.

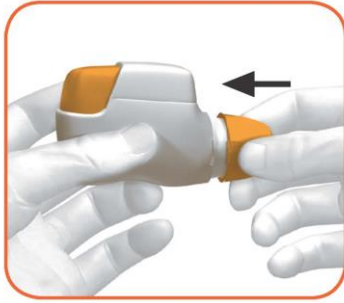


Figure M

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.

Each time you load a dose by pressing the orange 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.

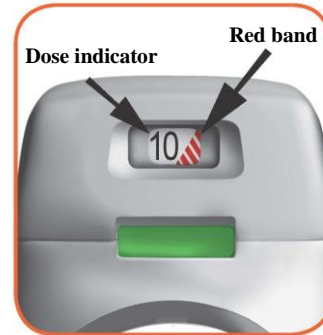


Figure N

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 orange 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 orange 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, DUA KLIR GENUAIR can cause side effects, although not everybody gets them.

Side effects may include:

- inflammation or irritation of the nose and throat;
- headache;
- urinary tract infection;
- throat pain;
- dizziness;
- muscle pain, cramps, spasms;
- flu;
- difficulty sleeping (insomnia);
- tooth infection;
- chest pain;
- shaking/tremor;
- cough;
- dry mouth;
- anxiety, agitation;
- rash, skin itching;
- distorted sense of taste;
- blurred vision;
- increased blood pressure;
- swelling of the hands or feet;
- inflammation of the mouth (stomatitis);
- hoarseness (dysphonia).

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

DUA KLIR GENUAIR can cause abnormal blood test results such as decreased levels of potassium, increased blood sugar, and increased creatine phosphokinase. 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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Common			
Nausea and/or diarrhea	√		

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	
Uncommon			
Decreased levels of potassium in the blood: muscle weakness, twitching and/or irregular heartbeat		√	
Increased blood sugar: frequent urination, thirst and hunger		√	
Palpitations, unusually fast or irregular heart beat		√	
Difficulty and pain passing urine or a feeling that your bladder has not completely emptied (urinary retention)		√	
Rare			
Paradoxical Bronchospasm: tightness of the chest associated with coughing, wheezing, or breathlessness immediately after inhalation of DUA KLIR GENUAIR			√
Glaucoma: New or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos of bright colours around lights, red eyes			√
Unknown			
Serious allergic reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Difficulty breathing		√	

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

HOW TO STORE IT

Store between 15 to 30°C.

Keep the DUA KLIR GENUAIR inhaler protected inside the sealed bag until you start to use it. Use the DUA KLIR GENUAIR inhaler within 60 days of opening the bag.

Keep DUA KLIR 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, carton and inhaler bag after "EXP". The expiry date refers to the last day of the month.

Do not use DUA KLIR 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.

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 or by contacting the sponsor, AstraZeneca Canada Inc. at: 1-800-668-6000.

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