New

Pr Aermony RespiClick™

fluticasone propionate
inhalation powder

It clicks

Every time the green cap is opened and it "clicks", one dose is ready to be inhaled.

If the patient does not hear the "click", the inhaler may not be activated to give a dose.

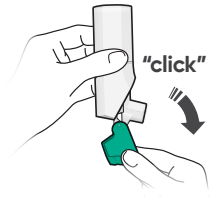
Aermony RespiClick™ is indicated for the maintenance treatment of steroid-responsive bronchial asthma as prophylactic therapy in patients 12 years of age and older.

Open up to a new option in asthma management.

teva | Respiratory

To use:
Open. Inhale. Close.

1



Open.

OPEN the cap all the way until patient feels and hears a "click"—once the cap clicks, one dose is ready to be inhaled.

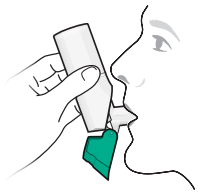
Instruct patients not to open the green cap unless they are taking a dose.

Before inhaling, patients should:

- Hold the inhaler away from the mouth and breathe out as much air as comfortable—without breathing into the mouthpiece.
- Place the mouthpiece in the mouth and close their lips around it to form a good seal (without blocking the vent above the mouthpiece).

Advise patients to refer to the Patient Medication Information leaflet that came with their device for complete dosing, maintenance, and disposal information.

2



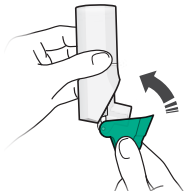
Inhale.

INHALE quickly and deeply through the mouth, until lungs feel completely full of air.

Instruct patients:

- To hold their breath for about 10 seconds (or as long as they comfortably can).
- That the dose of medicine is a very fine powder that they may not taste or feel, and they should not take an extra dose even if they do not taste/feel the medicine.

3



Close.

CLOSE the cap after inhaling so that the inhaler will be ready for the next dose.

Instruct patients to rinse out their mouths with water after taking their dose, and to spit out the water (instead of swallowing it).

Designed to “click” when the green cap is opened; plus additional key features[1]

Every time the green cap is opened and it “clicks”, one dose is ready to be inhaled. If the patient does not hear the “click”, the inhaler may not be activated to give a dose.

Does **not** require **priming**.

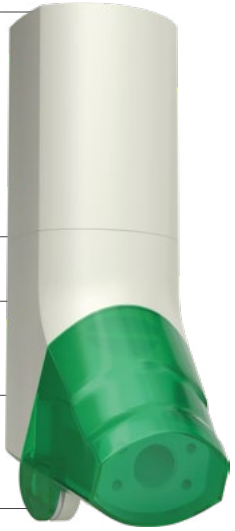
Loads the dose when the **attached green cap** is opened.

Patients should only open the cap when taking a dose. Opening and closing without taking a dose wastes medication and may damage the inhaler.

Dose is **breath-actuated**.

Should **not** be used with a **spacer** or volume holding chamber.

Has a **colour-coded dose counter** that shows how much of the medicine is left.



Aermony RespiClick™ core technology*,[2]

ACTIVE METERING

When the mouthpiece is opened:

Air from the pump applies pressure evenly to powder in the drug reservoir and one dose is metered into the dose cup.

CYCLONE SEPARATOR TECHNOLOGY

Ramps on the roof increase air turbulence.

Inhaled air enters through the tangential inlets; this creates the cyclonic air flow within the separator.

Fine drug particles are dispensed.

*Clinical significance has not been established.

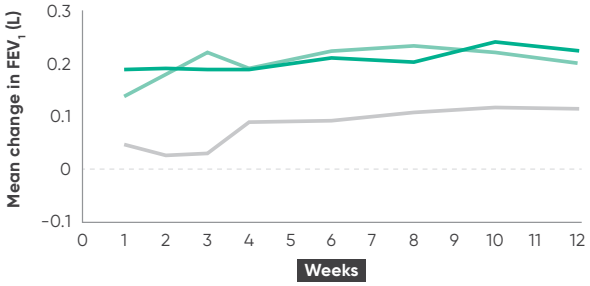
Aermony RespiClick™ vs. placebo: Changes from baseline in trough FEV_1 shown over 12 weeks

DEMONSTRATED EFFICACY:

Significantly greater improvements in trough FEV_1 shown vs. placebo at Week 12

MEAN CHANGE FROM BASELINE IN TROUGH FEV_1

Study 1:* Aermony RespiClick™ (55 mcg or 113 mcg) vs. placebo



Change from baseline in trough FEV_1 at Week 12:

- Aermony RespiClick™ 113 mcg BID (n=130)
  LS mean (SE): 0.204 (0.0340); 95% CI: 0.137; 0.271
- Aermony RespiClick™ 55 mcg BID (n=129)
  LS mean (SE): 0.172 (0.0347); 95% CI: 0.104; 0.240
- Placebo BID (n=130)
  LS mean (SE): 0.053 (0.0350); 95% CI: -0.015; 0.122

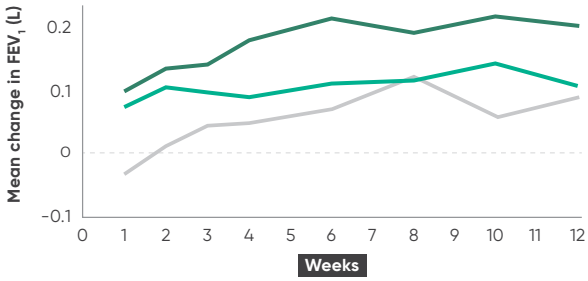
Adapted from Product Monograph.

LS MEAN DIFFERENCE FROM PLACEBO AT WEEK 12:	55 mcg BID	113 mcg BID
	0.119 (95% CI: 0.025, 0.212; *p*=0.0132)	**0.151** (95% CI: 0.057, 0.244; *p*=0.0017)

FEV_1: forced expiratory volume in 1 second; BID: twice daily; LS: least squares; SE: standard error; CI: confidence interval; $AUEC_{0-12h}$: area under the effect curve from 0 to 12 hours; LABA: long-acting beta agonist
*Study 1 was a randomized, double-blind, placebo-controlled, 12-week, global efficacy and safety trial that compared Aermony RespiClick™ 55 mcg and 113 mcg (one inhalation twice a day), Fluticasone/Salmeterol Multidose Dry Powder Inhaler 55/14 and 113/14 mcg (one inhalation twice a day), and placebo in 640 adolescents and adult patients with persistent symptomatic asthma despite low-dose inhaled corticosteroid (ICS) or ICS/LABA therapy. The primary endpoints were the change from baseline in trough FEV_1 at Week 12 for all patients and standardized baseline-adjusted FEV_1 $AUEC_{0-12h}$ at Week 12 analyzed for a subset of 312 patients who performed postdose serial spirometry.

MEAN CHANGE FROM BASELINE IN TROUGH FEV_1

Study 2:† Aermony RespiClick™ (113 mcg or 232 mcg) vs. placebo



Change from baseline in trough FEV_1 at Week 12:

- Aermony RespiClick™ 113 mcg BID (n=145)
  LS mean (SE): 0.119 (0.0311); 95% CI: 0.058; 0.180
- Aermony RespiClick™ 232 mcg BID (n=146)
  LS mean (SE): 0.179 (0.0308); 95% CI: 0.119; 0.240
- Placebo BID (n=143)
  LS mean (SE): -0.004 (0.312); 95% CI: -0.065; 0.057

Adapted from Product Monograph.

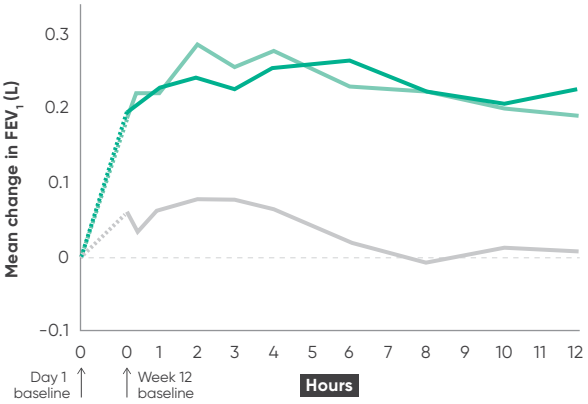
LS MEAN DIFFERENCE FROM PLACEBO AT WEEK 12:	113 mcg BID	232 mcg BID
	0.123 (95% CI: 0.038, 0.208; *p*=0.0047)	**0.183** (95% CI: 0.098, 0.268; *p*=0.0000)

†Study 2 was a randomized, double-blind, placebo-controlled, 12-week, global efficacy and safety trial that compared Aermony RespiClick™ 113 mcg and 232 mcg (one inhalation twice a day), Fluticasone/Salmeterol Multidose Dry Powder Inhaler 113/14 mcg and 232/14 mcg (one inhalation twice a day), and placebo in 720 adolescents and adult patients with persistent symptomatic asthma despite medium- or high-strength ICS or ICS/LABA therapy. The primary endpoints were the change from baseline in trough FEV_1 at Week 12 for all patients and standardized baseline-adjusted FEV_1 $AUEC_{0-12h}$ at Week 12 analyzed for a subset of 312 patients who performed postdose serial spirometry.

Aermony RespiClick™ vs. placebo: Improvements in FEV_1 sustained over 12 hours at Week 12

SERIAL SPIROMETRY: MEAN CHANGE FROM BASELINE IN FEV_1 AT WEEK 12 (FAS; serial spirometry subset)*

Study 1: Aermony RespiClick™ (55 mcg or 113 mcg) vs. placebo

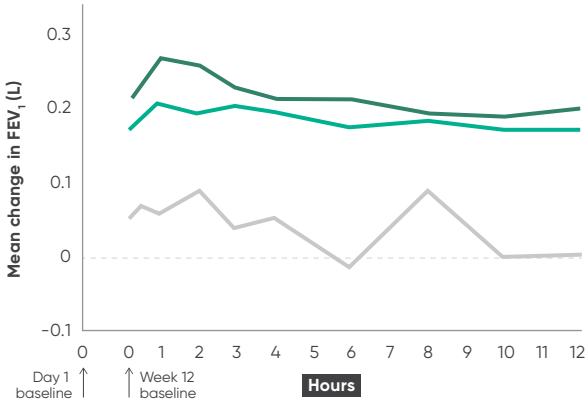


- Aermony RespiClick™ 113 mcg BID (n=69)
- Aermony RespiClick™ 55 mcg BID (n=58)
- Placebo BID (n=53)

Adapted from Product Monograph.

SERIAL SPIROMETRY: MEAN CHANGE FROM BASELINE IN FEV_1 AT WEEK 12 (FAS; serial spirometry subset)*

Study 2: Aermony RespiClick™ (113 mcg or 232 mcg) vs. placebo



- Aermony RespiClick™ 113 mcg BID (n=56)
- Aermony RespiClick™ 232 mcg BID (n=55)
- Placebo BID (n=41)

Adapted from Product Monograph.

In both studies, there was supportive evidence of efficacy for Aermony RespiClick™ (55 mcg, 113 mcg, and 232 mcg BID) compared with placebo for secondary efficacy variables such as:

- the weekly average of daily trough morning peak expiratory flow (A.M. PEF), and
- the total daily use of rescue medication.

The Asthma Quality of Life Questionnaire (AQLQ) for patients aged ≥ 18 years or the pediatric AQLQ (PAQLQ) for patients aged 12–17 years demonstrated improvement compared to placebo (secondary outcome).

FAS: full analysis set
*Standardized baseline-adjusted FEV, $AUEC_{0-12h}$ at Week 12 was analyzed for a subset of 312 patients (in each study) who performed postdose serial spirometry.

Aermony RespiClick™: A demonstrated safety profile

ADVERSE REACTIONS WITH ≥ 3% INCIDENCE WITH AERMONY RESPICLICK™ AND MORE COMMON THAN PLACEBO

Aermony RespiClick™ 55 mcg (n=129) (%)	Aermony RespiClick™ 113 mcg (n=274) (%)	Aermony RespiClick™ 232 mcg (n=146) (%)	Placebo (n=273) (%)
Nasopharyngitis			
5.4	5.8	4.8	4.4
Upper respiratory tract infection			
5.4	4.7	5.5	4.8
Oral candidiasis*			
3.1	2.9	4.8	0.7
Headache			
1.6	7.3	4.8	4.4
Cough			
1.6	1.8	3.4	2.6

*Oral candidiasis includes oropharyngeal candidiasis, oral fungal infection, and oropharyngitis fungal.
†Study 3 was a 26-week, randomized, open-label, active-controlled safety study of 674 adult and adolescent patients (aged 12 years and older) previously treated with ICSs or ICS/LABA combination therapy; 253 were treated twice daily with Aermony RespiClick™ 113 mcg or 232 mcg.

In a 26-week, open-label safety study, the types of adverse reactions shown were similar to those reported above from the placebo-controlled studies.†

ADVERSE DRUG REACTION OVERVIEW

In general, systemic and local corticosteroid use may result in:

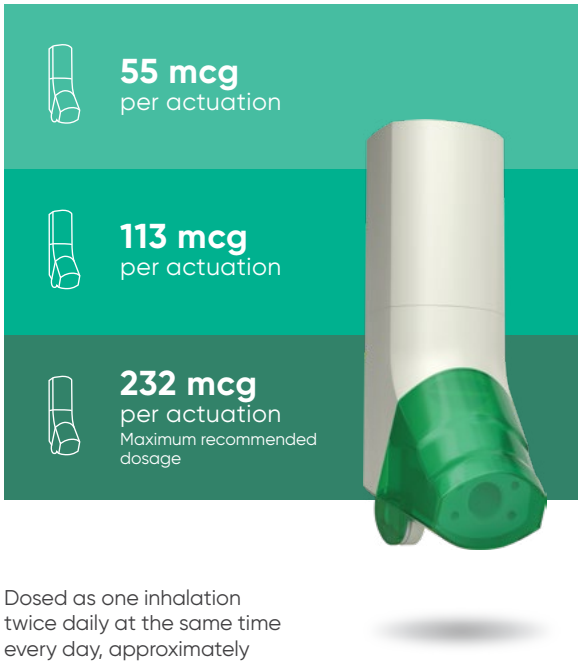
- Candidiasis
- Infections
- Hypercorticism and adrenal suppression
- Reduction in bone mineral density
- Effect on growth in pediatrics
- Glaucoma and cataracts

Please refer to the Product Monograph for more information.

Pr Aermony RespiClick™
fluticasone propionate inhalation powder

Dosing recommendations: How to start Aermony RespiClick™

AVAILABLE IN THREE DOSE OPTIONS



Dosed as one inhalation twice daily at the same time every day, approximately 12 hours apart.

Dosing recommendations: How to switch to Aermony RespiClick™

WHEN SWITCHING PATIENTS FROM THE FOLLOWING PRODUCTS

Recommended starting dose should be based on the strength of the previous product and level of disease severity.

Current therapy	Aermony RespiClick™ recommended starting dose
Bronchodilators alone	55 mcg twice daily
Inhaled corticosteroids	
Low dose	55 mcg twice daily
Medium dose	113 mcg twice daily
High dose	232 mcg twice daily

Use the lowest dose required to maintain good asthma control. When a patient's asthma is well controlled, a reduction in the dose should be attempted to identify the lowest possible dose required to maintain control. Such an attempt should be carried out on a regular basis.

If a dosage regimen fails to provide adequate improvement in asthma control, re-evaluate the therapeutic regimen. Additional therapeutic options should be considered.

If symptoms arise between doses, a breath-activated inhaled SABA should also be used for immediate relief.

SABA: short-acting beta$_2$-agonist

Important safety information

Clinical use:

Aermony RespiClick™ is not indicated for the relief of acute bronchospasm.

Efficacy and safety have not been established in children below 12 years of age.

Contraindications:

- Patients with a history of hypersensitivity to any of its ingredients.
- Patients with severe hypersensitivity to milk proteins.
- The primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

Relevant warnings and precautions:

- Not for acute use.
- Discontinuance: Risk of exacerbation.
- Risk of systemic effects.
- Patients transferred from systemic corticosteroid therapy.
- Patients sensitive to hypercorticism or adrenal suppression.
- Patients with major risk factors for decreased bone mineral density.
- Growth monitoring in pediatric and adolescent patients.
- Churg Strauss syndrome and eosinophilic conditions.
- Immediate hypersensitivity reactions after administration.
- Candidiasis.
- Increased susceptibility to infections.
- Glaucoma, increased intraocular pressure, cataracts, and central serous chorioretinopathy (CSCR).
- Paradoxical bronchospasm.
- Pregnancy.
- Breastfeeding.
- Patients with hepatic disease.
- Monitoring and laboratory tests.

For more information:

Consult the Product Monograph at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp for important information relating to adverse reactions, drug interactions, and dosing information that has not been discussed in this piece.

The Product Monograph is also available by calling us at 1-855-514-8382.

References: 1. Aermony RespiClick™ Product Monograph. Teva Canada. December 14, 2018. **2.** Zeng XM, Jones S, O'Leary D, et al. Delivery of formoterol from a novel multi-dose inhaler Airmax. *Respir Med*. 2002;96(6):397–403.

Pr Aermony RespiClick™

fluticasone propionate inhalation powder

New

Pr Aermony RespiClick™

fluticasone propionate
inhalation powder

When selecting an
inhaled corticosteroid...

Consider Aermony RespiClick™

BIOTECanada

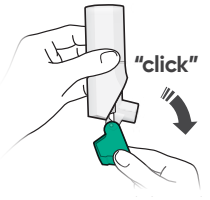
teva

PAAB

RC20-LBP01E

To use:
Open. Inhale. Close.

1



Open.

OPEN the cap all the way until patient feels and hears a "click"—once the cap clicks, one dose is ready to be inhaled.

Instruct patients not to open the green cap unless they are taking a dose.

Before inhaling, patients should:

- Hold the inhaler away from the mouth and breathe out as much air as comfortable—without breathing into the mouthpiece.
- Place the mouthpiece in the mouth and close their lips around it to form a good seal (without blocking the vent above the mouthpiece).

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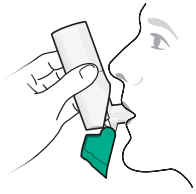
2



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Instruct patients:

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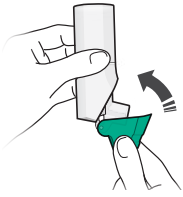

Close.

CLOSE the cap after inhaling so that the inhaler will be ready for the next dose.

Instruct patients to rinse out their mouths with water after taking their dose, and to spit out the water (instead of swallowing it).

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Every time the green cap is opened and it “clicks”, one dose is ready to be inhaled. If the patient does not hear the “click”, the inhaler may not be activated to give a dose.

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Dose is **breath-actuated**.

Should **not** be used with a **spacer** or volume holding chamber.

Has a **colour-coded dose counter** that shows how much of the medicine is left.

Aermony RespiClick™ core technology*,[2]

ACTIVE METERING

When the mouthpiece is opened:

Air from the pump applies pressure evenly to powder in the drug reservoir and one dose is metered into the dose cup.

CYCLONE SEPARATOR TECHNOLOGY

Ramps on the roof increase air turbulence.

Inhaled air enters through the tangential inlets; this creates the cyclonic air flow within the separator.

Fine drug particles are dispensed.

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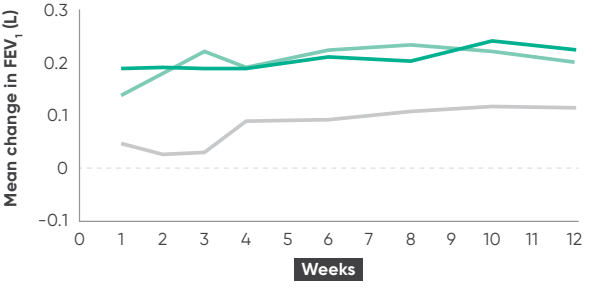
Aermony RespiClick™ vs. placebo: Changes from baseline in trough FEV_1 shown over 12 weeks

MEAN CHANGE FROM BASELINE IN TROUGH FEV_1

Study 1:* Aermony RespiClick™ (55 mcg or 113 mcg) vs. placebo



Change from baseline in trough FEV_1 at Week 12:

- Aermony RespiClick™ 113 mcg BID (n=130)
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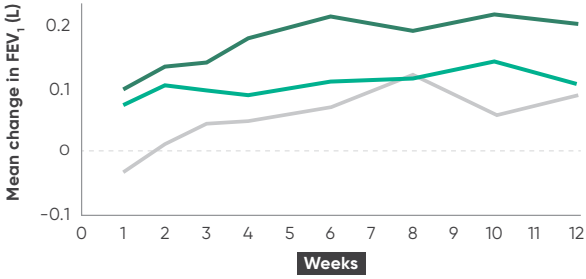
DEMONSTRATED EFFICACY:

Significantly greater improvements in trough FEV_1 shown vs. placebo at Week 12

MEAN CHANGE FROM BASELINE IN TROUGH FEV_1

Study 2:† Aermony RespiClick™ (113 mcg or 232 mcg) vs. placebo



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- Placebo BID (n=143)
  LS mean (SE): -0.004 (0.312); 95% CI: -0.065; 0.057

Adapted from Product Monograph.

LS MEAN DIFFERENCE FROM PLACEBO AT WEEK 12:	113 mcg BID	232 mcg BID
	0.123 (95% CI: 0.038, 0.208; *p*=0.0047)	**0.183** (95% CI: 0.098, 0.268; *p*=0.0000)

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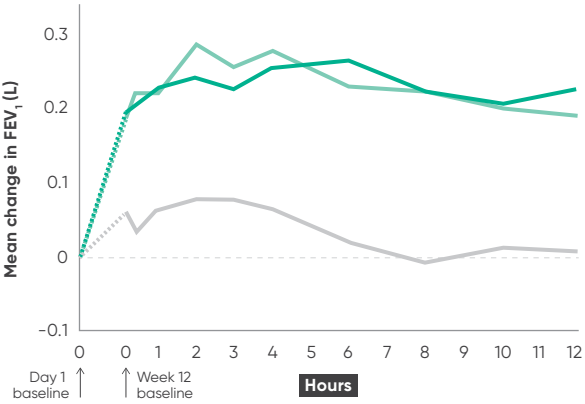
Aermony RespiClick™ vs. placebo: Improvements in FEV_1 sustained over 12 hours at Week 12

SERIAL SPIROMETRY: MEAN CHANGE FROM BASELINE IN FEV_1 AT WEEK 12 (FAS; serial spirometry subset)*

Study 1: Aermony RespiClick™ (55 mcg or 113 mcg) vs. placebo



Aermony RespiClick™ 113 mcg BID (n=69)
Aermony RespiClick™ 55 mcg BID (n=58)
Placebo BID (n=53)

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In both studies, there was supportive evidence of efficacy for Aermony RespiClick™ (55 mcg, 113 mcg, and 232 mcg BID) compared with placebo for secondary efficacy variables such as:

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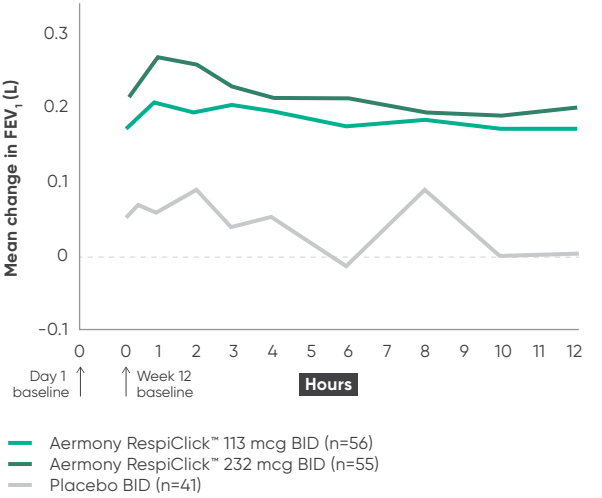

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Aermony RespiClick™: A demonstrated safety profile

ADVERSE REACTIONS WITH ≥ 3% INCIDENCE WITH AERMONY RESPICLICK™ AND MORE COMMON THAN PLACEBO

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Oral candidiasis*			
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Headache			
1.6	7.3	4.8	4.4
Cough			
1.6	1.8	3.4	2.6

*Oral candidiasis includes oropharyngeal candidiasis, oral fungal infection, and oropharyngitis fungal.
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- Hypercorticism and adrenal suppression
- Reduction in bone mineral density
- Effect on growth in pediatrics
- Glaucoma and cataracts

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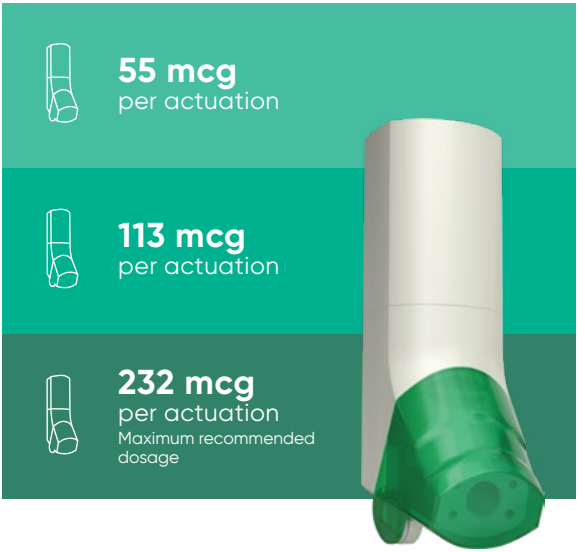
Pr Aermony RespiClick™
fluticasone propionate inhalation powder

Dosing recommendations: How to start Aermony RespiClick™

AVAILABLE IN THREE DOSE OPTIONS



Dosed as one inhalation twice daily at the same time every day, approximately 12 hours apart.

Dosing recommendations: How to switch to Aermony RespiClick™

WHEN SWITCHING PATIENTS FROM THE FOLLOWING PRODUCTS

Recommended starting dose should be based on the strength of the previous product and level of disease severity.

Current therapy	Aermony RespiClick™ recommended starting dose
Bronchodilators alone	55 mcg twice daily
Inhaled corticosteroids	
Low dose	55 mcg twice daily
Medium dose	113 mcg twice daily
High dose	232 mcg twice daily

Use the lowest dose required to maintain good asthma control. When a patient's asthma is well controlled, a reduction in the dose should be attempted to identify the lowest possible dose required to maintain control. Such an attempt should be carried out on a regular basis.

If a dosage regimen fails to provide adequate improvement in asthma control, re-evaluate the therapeutic regimen. Additional therapeutic options should be considered.

If symptoms arise between doses, a breath-activated inhaled SABA should also be used for immediate relief.

SABA: short-acting beta$_2$-agonist

Important safety information

Clinical use:

Aermony RespiClick™ is not indicated for the relief of acute bronchospasm.

Efficacy and safety have not been established in children below 12 years of age.

Contraindications:

- Patients with a history of hypersensitivity to any of its ingredients.
- Patients with severe hypersensitivity to milk proteins.
- The primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

Relevant warnings and precautions:

- Not for acute use.
- Discontinuance: Risk of exacerbation.
- Risk of systemic effects.
- Patients transferred from systemic corticosteroid therapy.
- Patients sensitive to hypercorticism or adrenal suppression.
- Patients with major risk factors for decreased bone mineral density.
- Growth monitoring in pediatric and adolescent patients.
- Churg Strauss syndrome and eosinophilic conditions.
- Immediate hypersensitivity reactions after administration.
- Candidiasis.
- Increased susceptibility to infections.
- Glaucoma, increased intraocular pressure, cataracts, and central serous chorioretinopathy (CSCR).
- Paradoxical bronchospasm.
- Pregnancy.
- Breastfeeding.
- Patients with hepatic disease.
- Monitoring and laboratory tests.

For more information:

Consult the Product Monograph at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp for important information relating to adverse reactions, drug interactions, and dosing information that has not been discussed in this piece.

The Product Monograph is also available by calling us at 1-855-514-8382.

References: 1. Aermony RespiClick™ Product Monograph. Teva Canada. December 14, 2018. **2.** Zeng XM, Jones S, O'Leary D, et al. Delivery of formoterol from a novel multi-dose inhaler Airmax. *Respir Med*. 2002;96(6):397–403.

Pr Aermony RespiClick™

fluticasone propionate inhalation powder