

Fluticasone Propionate Pressurized Metered Dose Inhaler Shortage

TABLE 1: SUPPLIERS OF FLUTICASONE PROPIONATE PRESSURIZED METERED DOSE INHALER (PMDI)¹

Product	Strength	DIN	Manufacturer
Flovent® pMDI	50mcg/actuation	02244291	GSK
	125mcg/actuation	02244292	
	250mcg/actuation	02244293	

Health Canada approved indications of orally inhaled fluticasone propionate²:

- the prophylactic management of steroid-responsive bronchial asthma in adults and children. For children, this includes patients not controlled on currently available prophylactic medication.

Note: This document addresses inhaled corticosteroid (ICS) treatment of **asthma**. ICS is one of the later steps in treatment of chronic obstructive pulmonary disease (COPD) and, therefore, should not be used as monotherapy.^{3,4} Some patients with more severe COPD may be using fluticasone propionate along with a combination long-acting beta agonist/long-acting muscarinic antagonist (LABA/LAMA); if so, consider:

- is ICS required? (Note: ICS may increase risk of pneumonia in patients with COPD)
- switch to triple combination inhaler (LABA/LAMA/ICS) (e.g. Trelegy Ellipta)
- switch to LABA/ICS combination with separate LAMA

Considerations and Non-Pharmacological Management⁵⁻⁷:

- Ensure proper inhaler technique and adherence.**
- Recommend smoking cessation when applicable.
- Identify and avoid triggers such as environmental allergens and occupational irritants.
- Treat conditions that may exacerbate: obesity, anxiety, depression, rhinitis, sinusitis, gastroesophageal reflux disease.
- Encourage physical activity.
- Have written action plans.

Pharmaceutical Alternatives:

- Flovent Diskus in varying strengths MAY be available, but will likely be shorted as inhaler stocks dwindle.
- It is possible some acute-care institutions are considering **Common Canister Protocols** to conserve pMDIs. Refer to the [article](#) published by the Institute for Safe Medication Practices (ISMP) which explains the premise as well as provides merits and potential risks of the policy.

Therapeutic Alternatives:

- Consider reserving fluticasone propionate 50mcg pMDI for pediatric use only recognizing that therapeutic alternatives are more limited in this population (see below).
- Switch to an available ICS at the approximate clinically comparable dose. See below Table 2 (≥12 years of age, including adults), Table 3 (children 6 to 11 years) and Table 4 (children 0 to 5 years).
- Products are comparable:
 - Adverse effects: at clinically comparable doses, ICSs are associated with similar tolerability.
 - One possible exception is that ciclesonide may be associated with fewer topical effects (e.g. oropharyngeal candidiasis) because it is a prodrug that remains inert until activated by esterases in the lung.⁵
 - Formulary Coverage⁷: All products included in the tables are full formulary for the Saskatchewan Drug Plan and Non-Insured Health Benefits.
 - Daily Doses
 - twice daily: fluticasone propionate, beclomethasone, budesonide
 - once daily: ciclesonide (except at higher doses), fluticasone furoate, mometasone (except at higher doses)
 - Cost⁷: ICS inhalers cost ~\$30-35 per device with the exceptions of:
 - beclomethasone (QVAR®): ~\$20
 - fluticasone furoate (Arnuity Ellipta): ~\$50

Note that nebulization is generally discouraged but should be further discouraged during the COVID-19 pandemic because nebulization may “generate a high volume of respiratory aerosols that may be propelled over a longer distance” thereby increasing risk of transmission to bystanders.^{8,9}

Pediatric Considerations:

- Ages 0-5 years:
 - Only fluticasone propionate pMDI and budesonide nebulules have Health Canada approval for use in this age group¹⁰ although some guidelines^{9,11} list beclomethasone pMDI and ciclesonide pMDI as suitable options.
- Ages 0-3 years:
 - The preferred inhaler device is pMDI via valved spacer with face mask.⁶ Nebulization with face mask would be an alternative option⁶, but not preferred during respiratory illness, such as COVID-19.⁸
 - Children of this age are likely not able to achieve the forceful breath inspiration required for correct use of dry powder inhalers (DPIs) (e.g. Diskus, Ellipta, Turbuhaler, Twisthaler).¹²
- Ages 4-5 years:
 - The preferred inhaler device is pMDI via valved spacer with mouthpiece.⁶ Alternatives would be spacer with face mask or nebulizer with mouthpiece or face mask⁶, again keeping in mind risks of nebulization during respiratory illness.⁸
 - Children of this age may be able to properly use a DPI; assess on an individual basis.

Inhaled Corticosteroids (ICS) Doses by Age:

Please Note:

- Variations exist among different references; the below tables are largely based on Global Initiative for Asthma (GINA) guidelines, which considers **doses to be clinically comparable** (not dose equivalences), based on available studies and product information.⁶
- There are advantages and disadvantages to the various devices making some less appropriate for some patients. Patients for whom **device selection** may be important include children and those with reduced dexterity, those unable to achieve forceful inspiration, and those with dementia, for example. RxFiles has excellent resources to help [select the best device](#) and information on [inhaler technique](#) (Subscription to RxFiles or SHIRP <https://shirp.usask.ca/home> is required.).

TABLE 2: ADULTS AND ADOLESCENTS ≥12 YEARS OF AGE^{6,10}

Medication	Total Daily Dose in mcg			Doses per Day
	Low	Medium	High	
Fluticasone propionate (Flovent®) pMDI & Diskus	≤250	251-500	>500	2
Beclomethasone dipropionate (QVAR®) pMDI	≤200	201-400	>400	2
Budesonide (Pulmicort®) Turbuhaler	≤400	401-800	>800	2
Ciclesonide (Alvesco®) pMDI	≤200	201-400	>400	1 or 2 [†]
Fluticasone furoate (Arnuity®) Ellipta	100	N/A	200	1
Mometasone furoate (Asmanex®) Twisthaler	200	201-400	>400	1 or 2*

[†]Ciclesonide daily dose give once daily unless 800 mcg in which administered as 400 mcg twice daily.¹³

*Mometasone furoate: daily doses given as: 200 mcg: 200 mcg once daily; 400 mcg: 400 mcg once daily or 200 mcg twice daily; 800 mcg: 400 mcg twice daily¹⁴

N/A = not applicable; pMDI=pressurized metered dose inhaler

TABLE 3: CHILDREN 6 TO 11 YEARS OF AGE⁶

Medication	Total Daily Dose in mcg				Doses per Day
	Low	Medium	High	Max Dose per PM	
Fluticasone propionate (Flovent®) pMDI & Diskus	100-200	201-400	>400	400 ²	2
Beclomethasone dipropionate (QVAR®) pMDI	50-100	101-200	>200	200 ¹⁵	2
Budesonide (Pulmicort®) Turbuhaler	100-200	201-400	>400	400 ¹⁶	2
Budesonide (Pulmicort®) [†] nebulules	250-500	501-1000	>1000	2000 ¹⁷	2
Ciclesonide (Alvesco®) pMDI	100	101-200	>200	200 ¹³	1
Mometasone furoate (Asmanex®) Twisthaler	100-200	201-400	>400	100 ¹⁴	1 or 2*

[†]During COVID-19 pandemic, the use of nebulules is discouraged because of potential for aerosolization.⁸

*Extrapolation from adults: daily doses of 400 mcg administered as 400 mcg once daily or 200 mcg twice daily.¹⁴

PM= product monograph; pMDI = pressurized metered dose inhaler

TABLE 4: CHILDREN 0-5 YEARS OF AGE

Medication	Age Approved by HC ¹⁰	Total Daily Dose in mcg [†]			Doses per Day
		Low	Medium	Max Dose per PM	
Fluticasone propionate (Flovent®) pMDI	≥ 1 y	50-125 ⁴	126-250 ⁴	1-4 y: 200 ² ≥ 4 y: 400 ²	2
Beclomethasone dipropionate (QVAR®)* pMDI	≥ 5 y	100 ¹¹	200 ¹¹	N/A	2
Budesonide (Pulmicort®) [†] nebulus	≥ 3 m	250-500 ^{6,11}	501-1000 ^{6,11}	2000 ¹⁷	2
Ciclesonide (Alvesco®)* pMDI	≥ 6 y	100 ¹¹	200 ¹¹	N/A	1
Mometasone furoate (Asmanex®) Twisthaler	For children ≥ 4y, doses in Table 3 apply.				

*Agents do NOT have a Health Canada approved indication for use in this age group but are considered options for children ≥ 1 year.
[†]During COVID-19 pandemic, the use of nebulus is discouraged because of potential for aerosolization.
[‡]High doses of ICS are not recommended in this age group and referral to an asthma specialist is suggested if asthma is not controlled on a medium dose of ICS.¹¹
 HC = Health Canada; m=month(s); pMDI = pressurized metered dose inhaler; y = year(s)

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