

Dulamet[®]



Mometasone Furoate EP and Formoterol Fumarate Dihydrate EP

Composition

Dulamet[™] 100 HFA inhaler: Each puff delivers Mometasone Furoate EP 100 microgram and Formoterol Fumarate Dihydrate EP 5 microgram from the actuator and Mometasone Furoate EP 115 microgram & Formoterol Fumarate Dihydrate EP 5.5 microgram from the valve.

Dulamet[™] 200 HFA inhaler: Each puff delivers Mometasone Furoate EP 200 microgram and Formoterol Fumarate Dihydrate EP 5 microgram from the actuator and Mometasone Furoate EP 225 microgram & Formoterol Fumarate Dihydrate EP 5.5 microgram from the valve.

Indication

Dulamet[™] HFA inhaler is used for asthma as follows:

- **Dulamet[™]** is a prescription medicine used to control symptoms of asthma and prevent symptoms such as wheezing in people 12 years of age and older.

- **Dulamet[™]** contains Formoterol which is a Long Acting β_2 Agonist (LABA). When it is used alone increase the risk of hospitalizations and death from asthma problems.

Dulamet[™] contains an ICS and a LABA. When an ICS and LABA are used together, there is not a significant increased risk in hospitalizations and death from asthma problems.

- **Dulamet[™]** is not for adults and adolescent patients with asthma who are well controlled with an asthma control medicine, such as a low to medium dose ICS medicine. **Dulamet[™]** is for adults and adolescent patients with asthma who need both an ICS and LABA medicine.

Pharmacology

Mometasone furoate is an inhaled corticosteroid - ICS for short. Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the lungs can lead to breathing problems.

Formoterol fumarate is a long-acting beta-2 agonist - LABA for short. LABA medicines help the muscles around the airways of the lungs stay relaxed to prevent asthma symptoms, such as wheezing, cough, chest tightness, and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.

Dosage & Administration

Adult and adolescent patients aged 12 Years and older: Dosage is either 2 inhalations twice daily of **Dulamet[™] 200 HFA inhaler** or **Dulamet[™] 100 HFA inhaler**. When choosing the starting dosage strength of **Dulamet[™]**, consider the patients' disease severity, based on their previous asthma therapy, including the inhaled corticosteroid dosage, as well as the patients' current control of asthma symptoms and risk of future exacerbation. The maximum recommended dosage is two inhalations of **Dulamet[™] 200 HFA inhaler** twice daily (maximum daily dosage 800 mcg/20 mcg).

After each dose of **Dulamet[™]** (2 puffs), rinse your mouth with water. Spit out the water. Do not swallow it. This will help to prevent thrush in your mouth or throat.

Pregnancy & lactation

The use of this combination during pregnancy and lactation should be restricted to those patients in whom the benefits clearly outweigh the risk.

Side-effects

The most common side effects of this combination include inflammation of the nose and throat, inflammation of the sinuses, headache, flu, and upper respiratory infection.

Other less common side-effects include: serious allergic reactions, thrush in the mouth & throat, reduces adrenal function, increase in wheezing, lower bone mineral density in osteoporosis patient, slowed growth in children, glaucoma, blurred vision & hypokalemia.

Contraindication

This combination is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

This combination is contraindicated in patients with known hypersensitivity to Mometasone Furoate, Formoterol Fumarate, or any of the ingredients in this combination.

Use in Special Populations

Hepatic/Renal Impairment: There are no data regarding the specific use of this combination in patients with hepatic or renal impairment.

Geriatrics: The pharmacokinetics of this combination have not been specifically studied in the elderly population.

Drug Interactions

- Strong cytochrome P450 3A4 inhibitors: Use with caution. May cause increased systemic corticosteroid effects.

- Adrenergic agents: Use with caution. Additional adrenergic drugs may potentiate sympathetic effects

- Xanthine derivatives and diuretics: Use with caution. May potentiate ECG changes and/or hypokalemia.

- MAO inhibitors, tricyclic antidepressants, macrolides, and drugs that prolong QTc interval: Use with extreme caution. May potentiate effect on the cardiovascular system.

- Beta-blockers: Use with caution and only when medically necessary. May decrease effectiveness and produce severe bronchospasm.

- Halogenated hydrocarbons: There is an elevated risk of arrhythmias in patients receiving concomitant anesthesia with halogenated hydrocarbons.

Storage

Keep out of the reach of children. Store below 30°C protected from direct sunlight and heat. Keep away from contact of eyes. The container should not be punctured, broken or burnt even when apparently empty.

How supplied

Dulamet[™] 100 HFA Inhaler: Each Inhaler delivers 120 puffs.

Dulamet[™] 200 HFA Inhaler: Each Inhaler delivers 120 puffs.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

Dulamet™

Mometasone Furoate EP and
Formoterol Fumarate Dihydrate EP

HFA Inhaler
120 puffs



Remove the cap and shake the inhaler vigorously before each use.

প্রতিবার ব্যবহারের পূর্বে ক্যাপ খুলে ভালভাবে ঝাঁকিয়ে নিন।



Holding the inhaler well away from your mouth, breathe out gently (but not fully).

ইনহেলারটা মুখ থেকে একটু দূরে রেখেই ধীরে ধীরে শ্বাস ছাড়ুন কিন্তু পুরো শ্বাস ছাড়বেন না।



Place the mouthpiece in your mouth and close your lips around it.

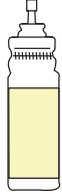
এ্যাকচুয়েটরের মুখ নিজের ঠোঁট দিয়ে এমনভাবে ধরুন যেন কোন ফাঁক না থাকে।



After starting to breathe in slowly and deeply through your mouth, press the metal canister firmly to release the powder, and continue to breathe in.

মুখ দিয়ে শ্বাস ভিতরে নিতে নিতে কেনিস্টারে চাপ দিন।

Parts of an Inhaler



Metal Canister



Dust Cap



Actuator



Remove the inhaler from your mouth and hold your breath for 10 seconds, or as long as it is comfortable, then breathe out slowly.

মুখ থেকে ইনহেলারটা সরিয়ে নিন এবং ১০ সেকেন্ড বা যতটুকু সম্ভব শ্বাস বন্ধ রাখুন, পরে ধীরে ধীরে শ্বাস ফেলুন।



If you take a second inhalation, you should wait for at least one minute before repeating steps 2,3 and 4. After use replace the cap on the mouthpiece.

দ্বিতীয় বার ইনহেলারের প্রয়োজন হলে কমপক্ষে ১ মিনিট অপেক্ষা করুন এবং একই পদ্ধতিতে আবার ব্যবহার করুন। ব্যবহারের পর ক্যাপ দিয়ে এ্যাকচুয়েটরের মুখ বন্ধ রাখুন।



Check your technique in front of a mirror from time to time, if you see a white mist during the inhalation you may not have closed your lips properly around mouthpiece, or you may not be breathing in as you press the can. This indicates failure of technique. If this happens, repeat the procedure from step 2 carefully.

আয়নার সামনে দাঁড়িয়ে পুরো পদ্ধতিটা মাঝে মাঝে অনুশীলন করুন। যদি কোন সাদা ধোঁয়া দেখতে পান তবে বুঝবেন যে ঠোঁট দিয়ে এ্যাকচুয়েটরের মুখ ভালভাবে ঢাকেননি অথবা আপনি চাপের সাথে সাথে শ্বাস নিচ্ছেন না। এটা পদ্ধতিগত ভুল। এমন হলে পদ্ধতিটি আবার চেষ্টা করুন।



It is very important that the plastic mouthpiece is to be cleaned regularly to prevent build-up of spare powder. Remove the metal canister and wash the plastic mouthpiece in warm water at least twice a week. Leave to dry in a warm place overnight. No harm will come with washing the mouthpiece every day. For further assistance / information please consult with your physician.

ক্যাপ ও এ্যাকচুয়েটর পরিষ্কার রাখা খুবই গুরুত্বপূর্ণ। ধাতব কেনিস্টার থেকে এ্যাকচুয়েটরটা খুলে হালকা গরম পানিতে সপ্তাহে কম পক্ষে দুইবার ধুয়ে নিতে হবে। প্রতিদিন ধুলেও কোন ক্ষতি নেই। ধোয়ার পর পর্যাপ্ত সময় শুক্স্থানে রেখে তকিয়ে নিন।

ইনহেলার এর ব্যবহারবিধি দেখতে QR কোডটি স্ক্যান করুন।



সাধনধারা :
প্রতিবার ব্যবহারের পর অবশ্যই কুলি করবেন।