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Dulera

## Dulera Inhaler do

Generic name: formoterol and mometasone [ for-MOE-ter-ol-and-moe-MET-a-sone ]

Brand name: Dulera

Drug class: Bronchodilator combinations

Medically reviewed by Philip Thornton, DipPharm. Last updated on Feb 19, 2025.

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## What is Dulera?

Dulera inhalers contain a combination of formoterol and mometasone. Formoterol is a long-acting bronchodilator that relaxes muscles in the airways to improve breathing.< Mometasone is a corticosteroid. It prevents the release of substances in the body that cause inflammation.

Dulera is used to control and prevent the symptoms of asthma in adults and children who are at least 5 years old.

Dulera is not for use in treating an asthma or bronchospasm attack.

## **Warnings**

**Dulera is not a rescue medicine for asthma attacks.** It will not work fast enough to treat an asthma or bronchospasm attack.

Formoterol when used alone may increase the risk of death in people with asthma. However, this risk is not increased when formoterol and mometasone are used together as a combination product.

Seek medical attention if your breathing problems get worse quickly, or if you think your asthma medications are not working as well.

## Before taking this medicine

You should not use Dulera if you are allergic to formoterol or mometasone.

Mometasone can weaken your immune system. Tell your doctor about any illness or infection you've had within the past several weeks.

To make sure Dulera is safe for you, tell your doctor if you have ever had:

· heart disease, high blood pressure;

- · a seizure;
- · a weak immune system;
- · liver disease:
- osteoporosis:
- glaucoma, cataracts, or other vision problems;
- · diabetes:
- a drug allergy;
- pheochromocytoma (tumor of the adrenal gland);
- a thyroid disorder; or
- an aneurysm (a weakened or damaged blood vessel that could tear and cause severe bleeding).

Tell your doctor if you are pregnant. It is not known whether formoterol and mometasone will harm an unborn baby. However, having untreated or uncontrolled asthma during pregnancy may cause complications such as low birth weight, premature birth, or eclampsia (dangerously high blood pressure that can lead to medical problems in both mother and baby). The benefit of treating asthma may outweigh any risks to the baby.

It may not be safe to breastfeed while using this medicine. Ask your doctor about any risk.

Dulera is not approved for use by anyone younger than 5 years old.

1 Dulera pregnancy and breastfeeding warnings (more detail)

## How should I use Dulera?

Dulera inhalers come with patient instructions for safe and effective use, and directions for priming the inhaler device. Follow these directions carefully. Use the medicine exactly as directed. Using too much of this medicine can cause life-threatening side effects. Ask your doctor or pharmacist if you have any questions.

**Dulera is not a rescue medicine for asthma attacks.** Use only fast-acting inhalation medicine for an attack. Seek medical attention if your breathing problems get worse quickly, or if you think your asthma medications are not working as well.

Read and carefully follow any Instructions for Use provided with your medicine. Ask your doctor or pharmacist if you do not understand these instructions.

Rinse your mouth with water without swallowing after each use of your Dulera inhaler.

Do not allow a young child to use this medicine without help from an adult.

It may take up to 1 or 2 weekss before your symptoms improve. Keep using the medication as directed and tell your doctor if your symptoms do not improve. Your doctor may tell you to stop using Dulera once your asthma is well controlled.

Your dose needs may change due to surgery, illness, stress, or a recent asthma attack. **Do not change your medication dose or schedule without your doctor's advice.** 

If you use a peak flow meter at home, tell your doctor if your numbers are lower than normal.

Your vision and your bone mineral density may need to be checked often.

Store at room temperature away from moisture and high heat. The canister may explode if it gets too hot. Do not puncture or burn an empty inhaler canister.

The 120-inhalation Dulera inhaler does not require specific storage orientation. For the 60-inhalation Dulera inhaler, after priming, store the inhaler with the mouthpiece down or on its side. Keep the medicine canister away from open flame or high heat, such as in a car on a hot day. The canister may explode if it gets too hot. Do not puncture or burn an empty inhaler canister.

Once your asthma is under control, your doctor may want you to stop using this medicine. **Do not stop using the medicine unless your doctor tells you to.** 

## **Dosing information**

#### Usual Adult Dose of Dulera for Asthma -- Maintenance:

Two inhalations inhaled orally twice daily (morning and evening).

Each inhalation contains either 100 mcg or 200 mcg of mometasone with 5 mcg of formoterol.

Maximum Daily Dose: 800 mcg of mometasone; 20 mcg of formoterol

#### Comments:

- -The starting dose should be determined based on patient's previous asthma therapy.
- -Patients previously on inhaled medium dose corticosteroids should be started on the 100 mcg/5 mcg strength.
- -Patients previously on inhaled high dose corticosteroids should be started on the 200 mcg/5 mcg strength.
- -Not for use in treatment of acute bronchospasm.

### **Usual Pediatric Dose for Asthma -- Maintenance:**

For children 12 years of age and older:

Two inhalations inhaled orally twice daily (morning and evening).

Each inhalation contains either 100 mcg or 200 mcg of mometasone with 5 mcg of formoterol.

Maximum Daily Dose: 800 mcg of mometasone; 20 mcg of formoterol

### Comments:

- -The starting dose should be determined based on patient's previous asthma therapy.
- -Patients previously on inhaled medium dose corticosteroids should be started on the 100 mcg/5 mcg strength.
- -Patients previously on inhaled high dose corticosteroids should be started on the 200 mcg/5 mcg strength.
- -Not for use in treatment of acute bronchospasm.

Use: Indicated for patients 12 years of age and older who have inadequate control on a long-term asthma control medication or whose disease severity requires initiation of an inhaled corticosteroid and long-acting beta2-adrenergic agonist



## What happens if I miss a dose?

Skip the missed dose and use your next dose at the regular time. Do not use two doses at one time.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Overdose symptoms may include chest pain, fast heart rate, and feeling shaky or short of breath.

## What should I avoid while using Dulera?

Do not use a second inhaled bronchodilator that contains formoterol or a similar medicine (such as arformoterol, indacaterol, olodaterol, salmeterol, or vilanterol).

Avoid being near people who are sick or have infections. Call your doctor for preventive treatment if you are exposed to chickenpox or measles. These conditions can be serious or even fatal in people who are using a medicine that contains mometasone (a steroid).

## **Dulera side effects**

Get emergency medical help if you have **signs of an allergic reaction to Dulera:** hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have:

- · worsening asthma symptoms;
- tremors, nervousness, chest pain, fast or pounding heartbeats;
- fever, chills, cough with mucus, feeling short of breath;
- wheezing, choking, or other breathing problems after using this medication;
- blurred vision, tunnel vision, eye pain or redness, or seeing halos around lights;
- signs of thrush (a fungal infection) sores or white patches in your mouth or throat, trouble swallowing;
- high blood sugar increased thirst, increased urination, dry mouth, fruity breath odor;
- low potassium level leg cramps, constipation, irregular heartbeats, fluttering in your chest, numbness or tingling, muscle weakness or limp feeling; or
- signs of a hormonal disorder tiredness or weakness, feeling light-headed, nausea, vomiting.

Mometasone can affect growth in children. Tell your doctor if your child is not growing at a normal rate while using this medicine.

Common Dulera side effects may include:

- runny or stuffy nose, sinus pain;
- · headache; or
- · cough, sore throat.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**1** <u>Dulera side effects</u> (more detail)

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## What other drugs will affect Dulera?

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Tell your doctor about all your other medicines, especially:

- antifungal medicine such as ketoconazole; or
- medicine to treat HIV (especially if it contains cobicistat, lopinavir, or ritonavir).

This list is not complete. Other drugs may interact with formoterol and mometasone, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

<u>Dulera drug interactions</u> (more detail)

## Does Dulera interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



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## Related treatment guides

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## **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Dulera only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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#### **DRUG STATUS**

#### **Availability**

Rx Prescription only

### **Pregnancy & Lactation**

ন্ত Risk data available

#### **CSA Schedule\***

N/A Not a controlled drug

#### **Approval History**

Drug history at FDA

#### **WADA Class**

്റ്റ് Anti-Doping Classification

### **User Reviews & Ratings**

5.8 / 10

61 Reviews

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