PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DULERA® Inhaler 200/5 µg (Pressurised metered-dose inhaler, liquid suspension)

mometasone furoate and formoterol fumarate dihydrate

Read all of this leaflet carefully before you start using DULERA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or your pharmacist, nurse or other healthcare provider.
- DULERA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DULERA is and what it is used for
2. What you need to know before you use DULERA
3. How to use DULERA
4. Possible side effects
5. How to store DULERA
6. Contents of the pack and other information

1. What DULERA is and what it is used for

DULERA is a metered-dose inhaler. DULERA 200/5 µg is a combination of mometasone furoate and formoterol fumarate dihydrate for oral inhalation only.

DULERA is used in adults and children 5 years of age and older to manage asthma and chronic obstructive pulmonary disease (COPD).

2. What you need to know before you use DULERA

Do not use DULERA:

- If you are hypersensitive (allergic) to mometasone furoate, formoterol fumarate dihydrate or any other ingredients in DULERA.
- If you have active or inactive tuberculosis.

Warnings and precautions

- DULERA is an asthma “preventer”. Do not use this medicine to relieve a sudden asthma attack. You should always carry the bronchodilator your doctor has prescribed, just in case you experience a sudden attack of asthma.
- Tell your doctor if you develop thrush (white patches in your mouth or on your throat), because if this occurs, it needs treatment. Your doctor may tell you to use another medicine to treat the thrush condition. You probably will be able to continue using DULERA during this treatment.
- Tell your doctor **immediately** if you have an asthma attack that does not improve after you use a bronchodilator during treatment with DULERA. You may require a change in medicine.
- Seek medical assistance **immediately** if you think you are having an allergic reaction to DULERA (sudden onset of wheezing or difficulty in breathing shortly after using this medicine).

- If you are presently taking oral cortisone to control or treat your asthma, your doctor will advise you on adjusting the dosage.
- Avoid exposure to chicken pox and measles and notify your doctor if exposed. This is important if you are taking any cortisone-type medicine and your immune system is not functioning well (if you have difficulty in fighting infection).
- Tell your doctor if you have an infection (of the eye, inside the body or on the body).
- DULERA, especially when used for a long time, may interfere with the usual growth pattern in children and growing adolescents. You may want to discuss this with your doctor.
- If you are taking a medicine called linezolid.
- If you are diabetic. DULERA may increase blood sugar levels. Tell your doctor if you are diabetic.
- If you have high blood pressure or you have ever had a heart problem. DULERA may affect existing heart problems.
- If you have low levels of potassium in your blood. DULERA may cause a decrease in potassium levels.
- If you have problems with your thyroid or adrenal gland function. DULERA may affect your adrenal gland function and/or thyroid function.
- If you have ever had tuberculosis (TB). (See **Do not use DULERA**).
- If you have herpes simplex (virus) infection of the eye or any other type of untreated infections.
- If you develop pneumonia and other lower respiratory tract infections in patients with COPD.
- If you experience visual disturbances including blurred vision.
- DULERA is not recommended for use in children under 5 years as safety and efficacy have not been demonstrated.

Other medicines and DULERA

Always tell your doctor, pharmacist or healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Beta-blocker medicines, such as atenolol or propranolol for high blood pressure, including eye drops such as timolol for glaucoma.
- Diuretics (water tablets), such as furosemide or hydrochlorothiazide.
- Xanthine medicines, such as theophylline or aminophylline. These are often used to treat asthma.
- Medication for a fast or uneven heartbeat, such as quinidine.
- Tricyclic antidepressants, such as amitriptyline.
- Macrolides (a class of antibiotics), including erythromycin, clarithromycin and azithromycin.
- Inhalation medicines which are used in anaesthesia.
- Monoamine oxidase inhibitors (MAOIs) used for depression. Linezolid is an antibiotic which also inhibits MAO.
- Ketoconazole or itraconazole (medicines to treat fungal infections).
- Cortisone (by mouth or by injection).
- Other medicines containing long-acting beta$_2$-agonists, such as salmeterol.
- Ritonavir (a medicine to treat HIV)

If any of the above applies to you or if you are not sure, talk to you doctor or pharmacist before using DULERA.

Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been demonstrated.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice before taking DULERA.

Driving and using machines

DULERA may cause dizziness.

Do not drive or use any tools or machines if you feel tired, sleepy or dizzy from the use of DULERA.

3. How to use DULERA

Do not share medicines prescribed to you with any other person.

Always use DULERA exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

The usual dose is 2 puffs in the morning and 2 puffs in the evening.

It is important to use DULERA every day, even if you have no symptoms at the time. Be in an upright position when inhaling DULERA.

Your doctor will tell you how long your treatment with DULERA will last. Do not stop treatment early. If you have the impression that the effect of DULERA is too strong or too weak, tell your doctor or pharmacist.

Note: Adults may assist children with using DULERA as prescribed. Children may use DULERA with or without a spacer device.

Instructions for use

The parts of your DULERA inhaler:

There are 2 main parts to your DULERA inhaler - the metal canister that holds the medicine and the blue plastic actuator. The inhaler also has a green cap that covers the mouthpiece of the actuator (see **Figure 1**). The inhaler contains 120 actuations (puffs).

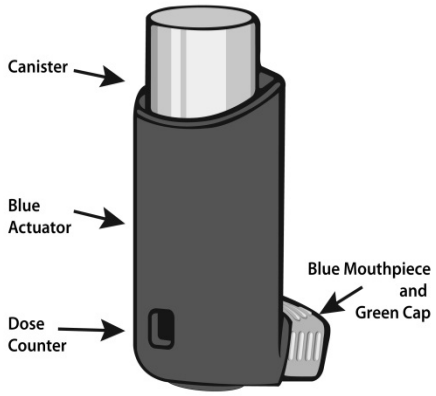


Figure 1

The inhaler comes with a dose counter located on the plastic actuator (see **Figure 1**). The counter display will show the number of actuations (puffs) of medication remaining. The dose counter will initially display "124" actuations remaining. Each time you press the canister, a puff of medicine is released, and the counter will count down by one. The counter will stop counting at 0.

You should not remove the canister from the actuator because:

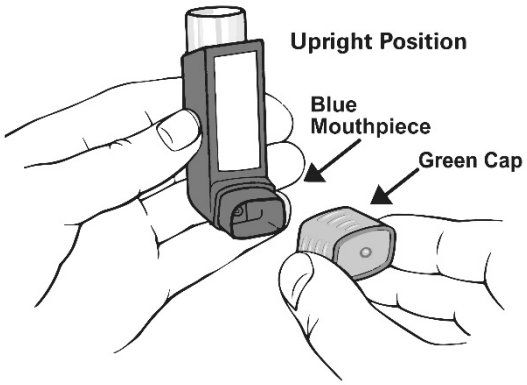
- You may not receive the correct amount of medication.
- The dose counter may not function properly.
- Reinsertion may cause the counter to count down by 1 and discharge a puff.

Use the DULERA canister only with the actuator supplied with the product.

It is necessary to prime the inhaler into the air the first time it is used. Prime the inhaler by releasing four actuations (puffs) into the air, away from your face. Shake the inhaler well before each of the priming actuations. After priming 4 times, the dose counter should read "120". It is also necessary to prime the inhaler when it has not been used for > 5 days using four actuations (puffs).

Using your DULERA inhaler:

1. Remove the cap from the mouthpiece of the actuator (see **Figure 2**). Check the mouthpiece for foreign objects prior to use. Make sure the canister is fully inserted into the actuator.
2. Shake the inhaler well immediately before each use.
3. Breathe out as fully as you comfortably can through the mouth, pushing out as much air from your lungs as possible. Hold the inhaler in the upright position and place the mouthpiece into your mouth (see **Figure 3**). Close your lips around the mouthpiece.



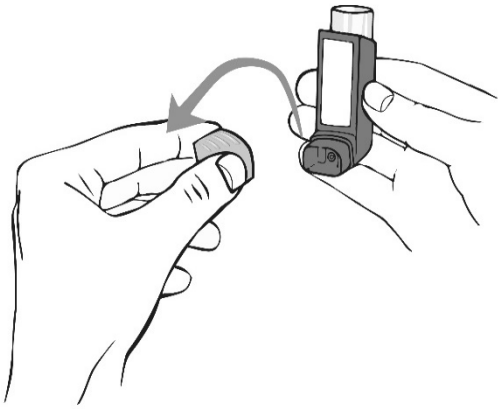


Figure 2



Figure 3

4. While breathing in deeply and slowly through the mouth, press down firmly and fully on the canister top until it stops moving in the actuator. Take your finger off the canister.
5. When you have finished breathing in, hold your breath as long as you comfortably can, up to 10 seconds. Then remove the inhaler from your mouth and breathe out through your nose, while keeping your lips closed.
6. For administration of the second actuation (puff), wait at least **30 seconds,** shake the inhaler well again and repeat steps 3 through 5.
7. Replace the cap immediately after use (see **Figure 4**).

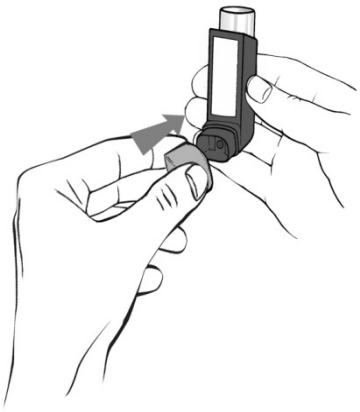


Figure 4

8. After completing both inhalations, you should rinse your mouth thoroughly with water and spit out the contents without swallowing.

When to replace your DULERA inhaler

When the counter reads 20, you should refill your prescription or ask your doctor if you need a new prescription for DULERA. Discard DULERA after your counter reaches 0, indicating that you have used the number of actuations (puffs) on the product label and box. Your inhaler may not feel empty and it may continue to operate, but you will not get the right amount of medicine if you keep using it.

Never try to change the numbers on the counter or remove the counter from the actuator.

Do not use the inhaler after the expiration date.

How to clean your DULERA inhaler

The mouthpiece should be cleaned using a dry wipe after every 7 days of use.

Routine cleaning instructions:

Remove the cap off the mouthpiece. Wipe the inside and outside surfaces of the actuator mouthpiece with a clean, dry, lint-free tissue or cloth. **Do not wash or put any parts of your inhaler in water.** Put the cap back on the mouthpiece after cleaning. Do not remove the canister from the actuator.

Do not attempt to unblock the actuator with a sharp object, such as a pin.

If you use more DULERA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The most common symptoms that may occur if you use more DULERA than you should are nausea, vomiting, headache, trembling, drowsiness, low potassium levels, high sugar levels, or a rapid or irregular heartbeat.

If you used larger doses for a longer period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of DULERA may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use DULERA

If you missed a dose, take it as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop using DULERA

Do not suddenly stop using this medicine even if your asthma seems to be better. Speak with your doctor first.

Your symptoms may come back if you stop using this medicine before your doctor has told you to do so. If you think that your asthma is not getting any better or seems to be getting worse after you have started using DULERA, go back and see your doctor.

4. Possible side effects

DULERA can have side effects.

Not all side effects reported for DULERA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DULERA, please consult your doctor, pharmacist or other healthcare professional for advice.

If you have any of the following symptoms soon after taking DULERA, **STOP** taking this medication and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Redness and swelling of eyelids, face, lips and throat.
- Lumpy skin rash or “hives” and itching anywhere on the body.

If you have them, you may have a serious allergic reaction to DULERA. You may need urgent medical attention or hospitalisation.

If an increase in wheezing occurs immediately after inhaling DULERA, use your short-acting bronchodilator "reliever" inhaler and contact your doctor immediately.

Advise your doctor or your pharmacist as soon as possible if you are bothered by any of the following effects which may occur: Candida infection (thrush) in the mouth or throat (white patches), headache and difficulty speaking (dysphonia).

Tell your doctor if you notice any of the following side effects:

Less Frequent: Pharyngitis (sore throat), bronchospasm (difficulty breathing), allergic dermatitis (itchy or irritated skin rash), urticaria (burning or stinging skin rash), insomnia (difficulty falling asleep), nervousness, tremor, dizziness, lens disorders, increased intraocular pressure (high pressure in the eye), blurred vision, tachycardia (fast heart beat), palpitations, hypertension (high blood pressure), pharyngolaryngeal pain (pain or discomfort in nose, mouth or voice box), throat irritation, nausea, dry mouth, muscle spasm, oral pain, diabetes mellitus (high blood sugar), dysgeusia (taste disturbances), somnolence (sleepiness) and pruritus (itchy skin).

If any of the side effects gets serious, please tell your doctor or pharmacist.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DULERA.

5. How to store DULERA

Store at or below 25 °C. Do not freeze. Shake well before use.

Keep out of reach of children.

Do not use this medicine after the month and year following EXP.: on the carton.

6. Contents of the pack and other information

What DULERA contains

The active ingredients in DULERA are mometasone furoate and formoterol fumarate dihydrate.

DULERA Inhaler 200/5 µg: Each metered dose delivers 200 µg of mometasone furoate and 5 µg of formoterol fumarate dihydrate.

The other ingredients are: hydrofluoroalkane (HFA-227), anhydrous alcohol, oleic acid.

What DULERA looks like and contents of the pack

The formulation is a white to off-white suspension contained within a pressurised canister with a metering valve.

The inhaler consists of a 16 mL aluminium canister internally coated with fluorinated ethylene/propylene copolymer (FEP), closed with a 50 mcl metering valve and a polypropylene press and breathe actuator with integrated dose counter and polypropylene mouthpiece cover.

The inhaler is stored in an outer carton.

DULERA 200/5 µg Inhaler is supplied as a pressurised metered-dose inhaler. Each inhaler contains 120 actuations (puffs).

Holder of certificate of registration

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