
Deventer 125/25 mcg/dose & 250/25 mcg/dose
Pressurized inhalation, metered dose aerosol can
Salmeterol & Fluticasone propionate

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using Deventer.

This leaflet answers some common questions about Deventer. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Deventer against the benefits this medicine is expected to have for you.

If you have any concerns about taking Deventer, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Deventer is used for

Deventer is available as a Metered Dose Inhaler (MDI) also known as an "inhaler".

Deventer is used to help with asthma and chronic obstructive pulmonary disease (COPD) in people who need regular treatment.

Asthma is a condition affecting the lungs. Symptoms of asthma include shortness of breath, wheezing, chest tightness and cough. Two main causes of asthma symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Chronic obstructive pulmonary disease (COPD) is a long-term condition affecting the lungs, resulting from chronic bronchitis or emphysema. Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up phlegm. The COPD symptoms are mainly due to bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Deventer contains two medicines, fluticasone propionate and salmeterol xinafoate.

Fluticasone propionate belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which are the steroids sometimes misused by athletes.

Corticosteroids have an anti-inflammatory action. They reduce the swelling and irritation in the walls of the small air passages in the lungs and so help you to breathe more easily. Corticosteroids are used to treat asthma and COPD.

Salmeterol xinafoate is a bronchodilator. A bronchodilator keeps the breathing tubes in your lungs open and relieves the symptoms of asthma and other chest conditions. The effects of salmeterol xinafoate last for up to twelve hours.

When taken together regularly fluticasone propionate and salmeterol help to control your breathing difficulties.

DO NOT use this medicine to treat a sudden attack of breathlessness as it will not help you. You will need a different type of medicine, e.g. salbutamol, which you must not confuse with Deventer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you use Deventer

When you must not use it

Do not take Deventer if you have an allergy to:

- any medicine containing fluticasone propionate
- any medicine containing salmeterol xinafoate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- wheezing or difficulty breathing
- swelling of the face, eyelids, lips/mouth, tongue or throat
- chest pain or tightness
- hay fever or lumpy rash ("hives")
- fainting

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If you use it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- thrush in your mouth
- tuberculosis
- diabetes
- a thyroid condition
- high blood pressure or a heart problem
- low blood potassium levels

Tell your doctor if you are taking other steroid medicines by mouth or inhalation

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Deventer.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines or have recently taken any other medicines, including any medicines that you buy without a prescription from a pharmacy, supermarket or health-food shop.

Some medicines and Deventer may interfere with each other. These include:

- Beta-blockers used to treat high blood pressure (hypertension)
- Ketoconazole used to treat fungal infection
- Ritonavir used to treat HIV infection

These medicines may be affected by Deventer or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this

medicine.

If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

How to use Deventer

Follow all directions given to you by your doctor carefully. They may differ from the information in this leaflet.

How much to take

It is very important that you use the medicine regularly every day. Do not stop treatment even if you feel better unless told to do so by your doctor.

Do not change your dose unless told to by your doctor.

If you are breathless or wheezing more often than normal, tell your doctor.

ASTHMA

Adults and adolescents 12 years and older:

Your doctor will prescribe 1 of 3 different strengths of Salmeterol/Fluticasone MDI for you, depending on the severity of your condition:

- Salmeterol/Fluticasone MDI 125/25 (125 micrograms of fluticasone propionate and 25 micrograms of salmeterol), or
- Salmeterol/Fluticasone MDI 250/25 (250 micrograms of fluticasone propionate and 25 micrograms of salmeterol).

The usual dose is two puffs from your inhaler twice a day.

COPD

Adults:

Your doctor will prescribe 1 of 2 different strengths of Salmeterol/Fluticasone MDI for you:

- Salmeterol/Fluticasone MDI 125/25 (125 micrograms of fluticasone propionate and 25 micrograms of salmeterol), or
- Salmeterol/Fluticasone MDI 250/25 (250 micrograms of fluticasone propionate and 25 micrograms of salmeterol).

The usual dose is two puffs from your inhaler twice a day.

How to use it:

The medicine in Deventer should be inhaled into your lungs.

Deventer must only be breathed in through the mouth.

Instructions for use

- Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the {invented name} properly or as prescribed may mean that it will not help your asthma as it should.
- The medicine is contained in a pressurised metal container in a plastic casing with a mouthpiece.
- There is a dose indicator in front of the inhaler which tells you how many doses are left. Each time you press the metal container, a puff of medicine is released and the dose indicator is counting down.
- Take care not to drop the inhaler as this may cause the dose indicator to count down.

Testing your inhaler

1. When using your inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.
2. To make sure that it works, shake it well, point the mouthpiece away from you and press the metal container to release a puff into the air. Repeat these steps until the dose indicator shows the number "120". Shake the inhaler immediately before releasing each puff. If you have not used your inhaler for a week or more,

remove the mouthpiece cover and shake the inhaler well (4 to 5 times). During the use of the inhaler the dose indicator counts down to zero.

Using your inhaler

It is important that you start breathing as slowly as possible before you use your inhaler.

1. Stand or sit upright when using your inhaler.
2. Remove the mouthpiece cover (picture 1). Check inside and outside to make sure that the mouthpiece is clean and free of objects.
3. Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed (picture 2).
4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable (picture 3).
5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite the mouthpiece (picture 4).
6. Breathe in through your mouth slowly and deeply. Just after starting to breathe in, press firmly down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply (picture 5).
7. Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler (picture 6). Continue holding your breath for a few seconds, or as long as is comfortable.
8. Wait about half a minute between taking each puff of medicine and then repeat steps 3 to 6.
9. Afterwards, rinse your mouth with water and spit it out or brush your teeth. This may help to stop you getting thrush and being hoarse.
10. After use always replace the mouthpiece cover straight away to keep out dust. When the mouthpiece cover is fitted correctly it will ‘click’ into position. If it does not ‘click’ into place, turn the mouthpiece cover the other way round and try again. Do not use too much force.



Do not rush steps 3,4, 5, and 6. It is important that you breathe in as slowly as possible just before using your inhaler. You should use your inhaler whilst standing in front of a mirror for the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth, you should start again from step 3.

As with all inhalers, caregivers/parents should ensure that children prescribed Deventer use correct inhalation

technique, as described above.

If you or your child find it difficult to use the Deventer, either your doctor or nurse or other healthcare provider may recommend using a spacer device with your inhaler. Your doctor, nurse, pharmacist or other healthcare provider should show you how to use the spacer device with your inhaler and how to care for your spacer device and will answer any questions you may have. It is important that if you are using a spacer device with your inhaler that you do not stop using it without talking to your doctor or nurse first. It is also important that you do not change the type of spacer device that you use without talking to your doctor. If you stop using a spacer device or change the type of spacer device that you use your doctor may need to change the dose of medicine required to control your asthma. Always talk to your doctor before making any changes to your asthma treatment.

Older children or people with weak hands should hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the base below the mouthpiece.

The dose counter is getting red when 40 doses are left. The counter is getting totally red when 20 doses are left to which tells decreased level of medicine. In this case you should consult your doctor. When the counter reaches 0, you should not use it as remaining medicine contains inadequate dose for you. You should not change number of counter or you should not try to remove the counter.

Cleaning your inhaler

To stop your inhaler blocking, it is important to clean it at least once a week.

To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the metal canister from the plastic casing at any time.
- Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue.
- Replace the mouthpiece cover. It will 'click' into place when fitted correctly. If it does not 'click' into place, turn the mouthpiece cover the other way round and try again. Do not use too much force.

DO NOT PUT THE METAL CANISTER INTO WATER.

Use your medicine as your doctor has told you. If you are not sure ask your doctor or pharmacist.

When to use it:

Your doctor has chosen this medicine to suit you and your condition. Deventer is used to help with asthma and COPD in people who need regular treatment.

It is very important that you use your Deventer every day, twice a day. This will help you to keep free of symptoms throughout the day and night.

Use your medicine at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you use this medicine before or after food.

How long to use it:

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to use Deventer

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, then go back to using it as you would normally.

Do not use a double dose to make up for the dose that you missed.

If you become wheezy or feel tight in the chest before the next dose is due, use a 'reliever puffer' in the usual

way. You should get relief from your 'reliever puffer' within a few minutes.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

In case of overdose

If you use too much (overdose)

Immediately telephone your doctor or contact the National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to the Emergency Department at your nearest hospital, if you think that you or anyone else may have used too much Deventer.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. **Keep the telephone numbers for these places handy.**

Symptoms of an overdose may include:

- rapid heart beat
- increased rate of breathing
- significant muscle tremor
- headache
- increased blood pressure
- increased blood sugar (glucose) levels

If you are not sure what to do, contact your doctor or pharmacist.

If you have any further questions on the use of Deventer, ask your doctor or pharmacist.

While you are using Deventer

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Deventer.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

It is important that all doctors treating you are aware that you are on inhaled steroids. If your body is stressed by, for example, severe infection, surgical operation, an accident etc, you may need steroid tablets or injections for a time.

If you become pregnant while taking this medicine, or are trying to become pregnant, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Contact your doctor if you experience a change in your vision.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not take Deventer to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you, or their symptoms seem similar to yours.

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of:

This medicine is not expected to affect your ability to drive a car or operate machinery. It is prudent to be careful driving or operating machinery until you know how Deventer affects you.

Side effects

Tell your doctor as soon as possible if you have any problems while taking Deventer, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

If your breathing or wheezing gets worse straight after using your MDI, stop using it immediately and tell your doctor as soon as possible.

This medicine helps most people with asthma and COPD. Most people using this medicine find that it causes no problem, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Common Side Effects

- soreness in the mouth, throat, or tongue
- hoarseness
- headache
- muscle cramps
- pains in joints
- increase in heart rate

Pneumonia (lung infection) has been reported commonly in patients with COPD.

Uncommon Side Effects

- skin rash
- shortness of breath
- sweating, trembling, feeling nervous or anxious
- bruising
- Eye problems (e.g. cataract, glaucoma)
- sleep disturbances

Rare Side Effects

- swelling of the face, lips, mouth, tongue or throat
- irregular heartbeat
- behavioural changes, including unusual activity and irritability (mainly in children).
- Rounded face
- Slowing of growth in children and adolescents

- Soreness in the oesophagus

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital, as you may be having an allergic reaction:

- wheezing or difficulty breathing
- swelling of the face, eyelids, lips/mouth, tongue or throat
- chest pain or tightness
- hay fever or lumpy rash ("hives")
- fainting

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Some side effects, for example changes in blood sugar (glucose) level, blood pressure or loss of bone density can only be found when your doctor does tests from time to time to check your progress.

Taking high doses of steroids for a long time could affect the adrenal glands, which make the body's own steroid. Your doctor may do tests to check how the adrenal glands are working.

Your doctor will be able to answer any questions you may have.

If you have any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

After using Deventer

Rinse mouth after use

Some people find that their mouth, throat or tongue becomes sore or that their voice becomes hoarse after inhaling this medicine. It may be helpful to rinse your mouth with water and spit it out after using your Deventer. Tell your doctor but do not stop treatment unless told to do so.

Storage

Keep this medicine out of the sight and reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Keep your Deventer in a dry place where the temperature stays below 30°C, away from direct heat or sunlight.

Do not store Deventer or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

If your Deventer MDI becomes very cold, it may not work properly. Keep your Inhaler away from frost.

WARNING: The Deventer MDI metal can is pressurised. Do not puncture or incinerate even when empty, as canister may explode.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Deventer is supplied to you in a metered dose inhaler which delivers your medicine in a pressurised suspension for you to inhale through your mouth into your lungs.

- One pressurised metal container delivers 120 actuations.
- The pressurised metal container contains a white to off white suspension for inhalation.
- The metal containers are fitted into a plastic casing incorporating a mouthpiece and fitted with dust caps.
- The inhalers are available in cartons which hold 1 or 3. Not all pack sizes may be marketed.

Ingredients

Active ingredient:

Deventer contains the active ingredients:

- fluticasone propionate
- salmeterol xinafoate

Deventer 125/25 mcg/dose

Each dose contains 125 micrograms of the active ingredient fluticasone propionate.

Each dose also contains 25 micrograms of active ingredient salmeterol.

Deventer 250/25 mcg/dose

Each dose contains 125 micrograms of the active ingredient fluticasone propionate.

Each dose also contains 25 micrograms of active ingredient salmeterol.

Other ingredients:

The other ingredient is propellant: norflurane (HFA 134a)

Sponsor

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Date of Preparation

This leaflet was prepared on 31.10.2022.