

SERETIDE[®] MDI (with counter)

Fluticasone propionate/Salmeterol xinafoate

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use Seretide MDI.

This leaflet answers some common questions about Seretide MDI. It does not contain all of 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 using Seretide MDI against the benefits this medicine is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Seretide MDI is used for

Seretide Metered Dose Inhaler (MDI) 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).

Seretide MDI 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 asthma.

Your doctor may have prescribed Seretide MDI for another reason.

Ask your doctor if you have any questions about why Seretide MDI has been prescribed for you.

The medicine in Seretide MDI is not addictive.

Before you use Seretide MDI

When you must not use it

- **Do not use Seretide MDI if you have ever had an allergic reaction to fluticasone propionate (Flixotide), salmeterol xinafoate (Serevent) or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

- **Do not use Seretide MDI if you are pregnant, trying**

to become pregnant or breast-feeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of using Seretide MDI if you are pregnant or breast-feeding.

- **Do not use Seretide MDI after the expiry date (EXP) printed on the pack.**

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

- **Do not use Seretide MDI if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be using Seretide MDI, talk to your doctor.

Before you start to use it

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines**
- **you are taking other steroid medicines by mouth or inhalation**
- **you are pregnant or likely to become pregnant**
- **you are breast-feeding**
- **you have ever had thrush in your mouth**
- **you are being or have ever been treated for tuberculosis (TB)**
- **you are having treatment for a thyroid condition**
- **you are having treatment for high blood pressure or a heart problem**

Using other medicines

Tell your doctor if you are using any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. For example, a class of medicines known as "beta-blockers" used to treat hypertension should be avoided. Other medicines like ketoconazole, used to treat fungal infection, and ritonavir used to treat HIV infection, may also affect how Seretide MDI works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

How to use Seretide MDI

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. Ventolin (salbutamol), which you must not confuse with Seretide.

How much to use

ASTHMA

Adults and adolescents 12 years and older: Your doctor will prescribe 1 of 3 different strengths of Seretide MDI for you, depending on the severity of your condition:

- Seretide MDI 50/25 (50 mcg fluticasone propionate and 25 mcg salmeterol) or
- Seretide MDI 125/25 (125 mcg fluticasone propionate and 25 mcg salmeterol) or
- Seretide MDI 250/25

(250 mcg fluticasone propionate and 25 mcg salmeterol)

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

Children 4 years and older:

The usual dose is two puffs from your Seretide MDI 50/25 (50 mcg fluticasone propionate and 25 mcg salmeterol) twice a day.

No information is available on use of Seretide MDI in children under 4 years old.

COPD

Adults: Your doctor will prescribe 1 of 2 different strengths of Seretide MDI for you:

- Seretide MDI 125/25 (125 mcg fluticasone propionate and 25 mcg salmeterol) or
- Seretide MDI 250/25 (250 mcg fluticasone propionate and 25 mcg salmeterol)

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

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.

How to use it

The medicine in the Seretide MDI should be inhaled into your lungs.

The full instructions for using Seretide MDI are given on a leaflet inside the pack.

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

If you have any difficulties or do not understand the instructions, ask your doctor or pharmacist.

Seretide MDI must only be breathed in through the mouth.

If your Seretide MDI is new and you have not used it before, you should release puffs into the air until the counter reads 120 to make sure that it works.

If your Seretide MDI has not been used for one week or more, you should release one puff into the air before use.

Each time a puff is released the number on the counter will count down by one.

In some cases dropping the inhaler may cause the counter to count down.

Cleaning:-

Your Inhaler should be cleaned at least once a week as follows:

1. Remove the mouthpiece cover.
2. Do not remove the canister from the plastic casing.
3. Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth or tissue .
4. Replace the mouthpiece cover.

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. Seretide MDI is used to help with asthma in people who need regular treatment.

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

Seretide MDI should not be used to relieve a sudden attack of breathlessness or wheezing.

If you get this sort of attack you must use a quick-acting inhaler (e.g. Ventolin).

If you feel you are getting breathless or wheezy more often than normal, or you are using your quick-acting inhaler more than usual, you should go to your doctor.

If you forget to use it

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 use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre

(telephone 131126) for advice, if you think you or anyone else may have used too much Seretide, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are using Seretide MDI

Things you must do

Tell your doctor or pharmacist that you are using Seretide MDI if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

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 stop using Seretide, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Seretide MDI to treat any other complaints unless your doctor says to.

Do not use Seretide MDI after the expiry date shown on the carton and label.

Things to be careful of

Be careful driving or operating machinery until you know how Seretide MDI affects you.

Seretide MDI generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Seretide MDI may cause dizziness/drowsiness/tiredness in some people.

Side-Effects

Check with your doctor as soon as possible if you have any problems while using Seretide MDI, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Most people using this medicine find that it causes no problem. Like other medicines, Seretide MDI can cause some side-effects. If side-effects occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- soreness of the throat or tongue
- hoarseness
- headache
- muscle cramps
- pains in joints

- skin rash
- trembling
- increase in heart rate

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

It is possible that some people, particularly those taking higher doses of Seretide MDI for a long time, may rarely suffer from the following side effects:

- rounded face
- loss of bone density
- eye problems (eg cataract, glaucoma)
- slowing of growth in children. It is unclear what, if any, difference this makes to a child's final height.

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.

It is important that:

- treatment with your Seretide MDI is not stopped suddenly.
- 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.

Very rarely the person taking the medicine may feel anxious, have disturbed sleep or notice increased irritability (mainly in children).

If you feel unwell in any other way or have any

symptoms that you do not understand, you should ask your doctor immediately.

If you think you are having an allergic reaction to Seretide MDI, STOP using this medicine and TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms of an allergic reaction usually include some or all of the following:

- wheezing
- swelling of the lips/mouth, tongue or throat
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After using Seretide MDI

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 Seretide MDI. Tell your doctor but do

not stop treatment unless told to do so.

Storage

Keep this medicine where young children cannot reach it.

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

Keep Seretide MDI in a dry place where it stays below 30°C, away from direct heat and sunlight.

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

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

WARNING: The metal can is pressurised. Do not burn it or puncture it, even when it is empty.

Disposal

If your doctor tells you to stop using Seretide MDI, or the Seretide MDI has passed its expiry date, ask your pharmacist what to do with any Seretide MDI left over.

Product description

What Seretide MDI looks like

Seretide MDI consists of a plastic casing which contains a small metal canister. The casing has a mouthpiece which is covered by a cap.

Each canister contains 120 doses of the medicine.

Each dose contains 50 or 125 or 250 micrograms of the active ingredient fluticasone propionate. Each dose also contains 25 micrograms of active ingredient salmeterol. The amount depends on which strength of Seretide you have been given.

The canister has a counter attached to show how many puffs of medicine you have left. The number of puffs left will show through a window in the back of the plastic casing. Each time the canister is pressed a dose of the medicine is released and the counter will count down by one.

You should consider getting a replacement when the counter shows the number 020. Do not use your Seretide MDI if the counter shows 000. When the counter shows 000 you must dispose of your Seretide MDI.

Never try to alter the numbers on the counter or detach the counter from the metal canister. The counter cannot be reset and is permanently attached to the canister.

Ingredients

Seretide MDI contains the active ingredients fluticasone propionate and salmeterol xinafoate.

Your Seretide MDI also contains HFA-134a, a CFC-Free propellant.

It does not contain gluten or sucrose.

Sponsor

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Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 28 March 2007.

The information provided applies only to Seretide[®] MDI.

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Seretide MDI 50/25: AUST R 120661
Seretide MDI 125/25: AUST R 120662
Seretide MDI 250/25: AUST R 120663

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Version 1.0