

medicineupdate

Asking the right questions about new medicines

Seretide – for chronic obstructive pulmonary disease

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get to know your medicines

to find out more about this medicine

- call Medicines Line on 1300 888 763 to speak to a pharmacist (Mon-Fri 9am-6pm EST – cost of a local call, mobile calls more)
- read the Consumer Medicine Information (CMI) for this medicine (available from your doctor or pharmacist, the consumer section at www.nps.org.au, or from the manufacturer).



National Prescribing Service Limited

NPS is an independent, non-profit organisation for Quality Use of Medicines, funded by the Australian Government Department of Health and Ageing.

When you are considering a new medicine, it is important to weigh up the expected benefits and the possible risks of the new medicine, compared with other available medicines or treatments.

Risks and benefits differ between medicines and from person to person.

Your doctor can help you compare different medicines and treatments to decide what is best for your particular situation.

1. What this medicine is

Seretide (pronounced se-re-tide) is an inhaler. It contains two active ingredients:

- **fluticasone** (pronounced **floo-tikka-sown**) and
- **salmeterol** (pronounced **sal-met-ah-roll**).

Fluticasone is a type of corticosteroid, which is part of the family of steroids. The body produces many different types of steroids, such as cortisone, oestrogen, progesterone and testosterone. These steroids have vital functions in the body. Steroids mainly become a problem if used without appropriate medical advice and supervision.

Corticosteroids help reduce inflammation. When inhaled, as in Seretide, they act directly on the lungs to reduce inflammation. Inflammation causes swelling and narrowing of the airways, and the production of mucus. It is an important feature of asthma and chronic obstructive pulmonary disease (COPD).

Salmeterol is a long-acting beta-agonist. This type of medicine helps the muscles around the airways in the lung relax. Long-acting means it usually lasts 12 hours or more.

So in combination, Seretide aims to reduce the inflammation in the lung and relax the airways.

The active ingredient is the chemical in the medicine that makes the medicine work.

2. What this medicine treats

Seretide treats some forms of lung disease, including chronic obstructive pulmonary disease, or COPD, and asthma.

COPD is chronic obstructive pulmonary disease, which may include illnesses like chronic bronchitis, emphysema, chronic asthma and others.

In COPD, the airways into the lungs become narrower. They also become inflamed. This makes it hard to breathe. Most of the narrowing is permanent, although some of it may be eased with treatment. The narrowing tends to get worse with time.

COPD usually begins after the age of 40, and often affects people who smoke or have smoked. If a person has mild COPD, quitting smoking can lead to an improvement in the function of the lungs. If a person has moderate to severe COPD, then quitting smoking can slow the speed at which the condition gets worse.

In asthma, the airways are easily irritated. Inhaling a variety of dusts, chemicals, allergic factors and so on may cause the muscle around the airways to tighten and to restrict the flow of air into and out of the lungs. Asthma symptoms tend to come and go over time.

3. Other medicines available for this condition

A number of medicines other than Seretide can be used to treat COPD. These include:

Medicines that relax the airways:

- short-acting beta agonists as a single medicine such as salbutamol (Airomir, Asmol, Butamol, Epaq, GenRx Salbutamol, Ventolin) and terbutaline (Bricanyl). These medicines relax the muscles around the airway quickly and last for 3-4 hours.
- short-acting anticholinergics such as ipratropium (Aeron, Apoven, Atrovent, DPL Ipratropium, GenRx Ipratropium, Ipratrin, Ipravent). These medicines also relax the muscles around the airway for 3-4 hours.
- long-acting beta agonists such as salmeterol as a single medicine (Serevent) and eformoterol (Foradile, Oxis). These medicines relax the muscles around the airway for 8-12 hours or more.
- long-acting anticholinergics such as tiotropium (Spiriva). These medicines relax the muscles around the airway for 12 hours or more.

Medicines that reduce inflammation in the airways:

- inhaled corticosteroids such as beclomethasone (Qvar), budesonide (Pulmicort), ciclesonide (Alvesco) and fluticasone as a single medicine (Flixotide) reduce inflammation in the airways.

Combination medicines that relax the airways and reduce inflammation:

- short-acting combination medicines such as ipratropium plus salbutamol (Combivent).
- long-acting beta-agonist and corticosteroid combination medicines such as budesonide plus eformoterol (Symbicort).

Seretide is an example of a combination medicine.

Only some of these medicines are subsidised through the PBS for all people with COPD. See Section 10 for details.

Guidelines developed by the National Institute for Health and Clinical Excellence in the UK (www.nice.org.au), and Australian guidelines developed by the Australian Lung Foundation (www.copdx.org.au), say the best way for doctors to treat a person with COPD is to try certain steps, one at a time, until the treatment works.

Step 1: start with regular doses of a short-acting medicine to relax the airways (a short-acting beta agonist or anticholinergic medicine).

Step 2, if needed, use both regularly.

Step 3, if needed, switch to a long-acting medicine to relax the airways (a long-acting beta agonist and/or an anticholinergic medicine).

Step 4, if needed, use both a long-acting medicine to relax the airways (beta agonist and/or anticholinergic medicine), plus an inhaled corticosteroid to reduce inflammation. This could be administered via separate inhalers, or as two medicines combined in one inhaler. Seretide is such a combination. It contains a long-acting beta agonist and an inhaled corticosteroid.

**Talk with your doctor
about all of the
treatment options for
COPD and asthma.**

4. **How well it works compared with other medicines**

It is difficult to compare Seretide with other medications, as there are no other directly comparable combination medicines approved for COPD. Below is a summary of how well Seretide works compared with other medicines which do similar, but not identical, things.

Research has shown that people with COPD who use both an inhaled corticosteroid and a long-acting beta agonist have fewer sudden exacerbations, or flare-ups, than people not using either medicine. That is, for people with COPD, using both medicines is better than not using either medicine with regard to flare-ups.

Different research shows that, for people with moderate to severe COPD, using an inhaled corticosteroid in combination with a long-acting beta agonist is better than using either one alone with regard to flare-ups.

Seretide has been shown to work better than either of its component parts alone – fluticasone or salmeterol – for improving the airflow of people with moderate to severe COPD.

Researchers have compared the annual death rate of people experiencing COPD and taking Seretide with the annual death rate of people taking a placebo (or dummy medicine). Overall, this research suggests Seretide might reduce the annual death rate slightly, but it is not certain.

It is unclear whether other similar combinations (such as Symbicort) or other different single agent medications (such as tiotropium) are as effective. It is also unproven whether combining Seretide with long-acting anticholinergic medications is even better than either one used alone.

In conclusion, Seretide will not work for everybody. It may be a matter of trial and error, working with your doctor, to see if it is effective.

5. **Important side effects to consider**

All medicines can have side effects. Sometimes the side effects are serious but most of the time they are not.

The most serious side effect associated with Seretide is a slightly increased risk of pneumonia, which causes fevers, chills, weakness and a worsening cough. The slightly increased risk of pneumonia is probably due to fluticasone, the steroid component of Seretide. Older people have a higher risk of severe pneumonia than younger people.

Other potential side effects include:

- thrush (candida) infection in the mouth and throat
- a hoarse or altered voice
- interference with the body's usual production of corticosteroids, which may cause problems when the medicine is stopped suddenly
- thinning of the skin, which can cause the skin to be more easily damaged
- easy bruising
- palpitations or a racing heart.

Thrush in the mouth and throat and a hoarse voice are fairly common, while the other side effects listed are fairly uncommon.

For a complete list of possible side effects, see the consumer medicine information leaflet for Seretide.

Talk to your doctor about the possible side effects of this medicine before you use it.

Always tell your doctor about any changes to your condition if you are taking a new medicine.

6.
How these side effects compare with other medicines

It is difficult to compare Seretide with other medicines used to treat COPD. But all the side effects listed above, except for the last one (palpitations or a racing heart), are probably due to the fluticasone component of Seretide.

Other medicines which do not contain a corticosteroid, like fluticasone, will not have the same potential for side effects, such as pneumonia, thrush in the mouth and throat, a hoarse voice, thin skin and easy bruising. Nor will they interfere with the body's usual production of corticosteroids.

7.
How to reduce your risk of side effects

Use the Seretide puffer with a spacer. After using Seretide, rinse your mouth with water, gargle and spit out the water. This will help reduce the risk of side effects such as thrush in the mouth and throat, and a hoarse voice.

The most important way to reduce the risk of side effects is to only use Seretide if it is working, and to use it at the dose prescribed. Excessive doses will increase the likelihood of side effects. If you and your doctor do not notice an improvement in your symptoms within 4 – 8 weeks, then you and your doctor should discuss stopping the medicine.

Ask your doctor how you can monitor whether the medicine is helping you.

8.
What else you should know about this medicine

Read the consumer medicine information (CMI) leaflet.

Before you start taking a new medicine, you should read the CMI leaflet. The CMI leaflet will tell you:

- who should not take the medicine
- which medicines should not be taken at the same time (drug interactions)
- how to take the medicine
- the most possible side effects
- the ingredients.

You can get the CMI for Seretide from:

- your doctor or pharmacist
- www.nps.org.au/consumers (click on 'Consumer Medicine Information' in the Quicklinks column on the left of the screen)
- GlaxoSmithKline Australia Pty Ltd, the makers of Seretide, on 1800 033 109 or at www.gsk.com.au.

Consumer medicine information leaflets are available for most prescription medicines.

9.
Who can be prescribed this medicine on the PBS

Seretide was first listed on the PBS for certain types of asthma in 2000.

In August 2007, the PBS listing was changed. Seretide is now also available through the PBS for people with COPD who:

- have repeated flare-ups with significant symptoms; and
- have poor lung function on a specific test known as the FEV1.

If you have either asthma or moderate to severe COPD and fit the criteria, you will be eligible to receive Seretide through the PBS. You will need to pay a PBS co-payment. At the time of publication, the co-payment was:

- \$31.30 for people without a concession card
- \$5.00 for concession card holders.

There are a number of different forms and strengths of Seretide. The Government has PBS approved only two forms for people with COPD – the Seretide inhaler 250/25 and the Seretide Accuhaler 500/50 (which is a dry powder inhaler). Other doses of Seretide have not been shown to be as effective in COPD, according to the PBS. However, other doses are still available if your doctor prescribes them, but they are not subsidised by the PBS.

For people who pay concessional prescription rates, a Seretide prescription costs the Australian Government \$72.70.

For people who do not pay concessional prescription rates, a Seretide prescription costs the Australian Government \$47.00.

Most medicines prescribed by your doctor are covered by the PBS. This means that the Australian government pays part of the cost of your medicine.

You will need to pay the full price if the medicine is not available on the PBS, or is not available on the PBS for your specific condition.

10.
Other ways to help this condition

The most important way to help this condition, for those who are still smoking, is to quit smoking. Quitting at any time helps – the health of people who quit starts to improve within days.

There are a number of ways to quit smoking, including:

- going cold turkey
- gradually reducing then quitting
- using nicotine replacement therapy or other medicines
- getting counselling.

All of these methods work for some people. It is helpful to discuss your own options with your general practitioner, who can provide or organise support and counselling during your attempts to quit and prescribe some of the effective medications. A pharmacist can provide specific assistance with nicotine replacement therapy. It often takes more than one attempt to quit smoking. If the first attempt doesn't work, try again. It is worth it.

Some hospitals and health services also run pulmonary (lung) rehabilitation classes. Ask your local doctor or your local hospital.

For more information, contact the Quitline on 131 848. (13 QUIT) or get yourself an online quitting coach from www.quitcoach.org.au

11.

How new medicines are tested and approved for use in Australia

Prescription medicines go through many tests and clinical trials before they can be prescribed in Australia. All medicines go through four types of tests to assess their effectiveness, side effects and safety:

- laboratory tests (not involving people)
- phase 1 clinical trials, typically with 20–80 healthy volunteers, to test the safety and dosage in people with normal physical health
- phase 2 clinical trials, typically with 100–500 volunteers with the condition, to test the effectiveness and safety
- phase 3 clinical trials, typically with 1000–3000 volunteers with the condition, to confirm the medicine's effectiveness and find out more about its side effects.

Sometimes, less common side effects do not become obvious until large numbers of people have used the medicine.

The Therapeutic Goods Administration (Australia's regulatory agency for medicines) checks these results before it approves the registration of the medicine for use in Australia.

Medicines are made available on the PBS if they are shown to be as good or better than other available medicines for the same condition.

Why Medicine Update?

Medicine Update lets you know about new drugs and new PBS listings. When medicines are new, less is known about their expected benefits and possible harms than for older medicines. It's important to understand what evidence is available about both benefits and harms. Medicine Update provides balanced information to help you decide if a medicine is right for you.

Who wrote Medicine Update?

National Prescribing Service Limited (NPS), an independent, non-profit, government-funded organisation, wrote this information in consultation with consumers and health professionals

Who is it for?

Medicine Update is written for people who are thinking about a new medicine, or have had a medicine suggested or prescribed for them and want to find out more.

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Visit the NPS website to find out about our free activities and resources for consumers www.nps.org.au/consumers



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