

Package leaflet: Information for the user

Roadasan Forspiro, 50 microgram/500 microgram/dose, inhalation powder, predispensed

salmeterol/fluticasone propionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Roadasan Forspiro is and what it is used for

Roadasan Forspiro is used to treat:

- asthma
- chronic obstructive pulmonary disease (COPD)
This disease is characterized by continuous breathing difficulties caused by narrowed airways, often accompanied with coughing and phlegm. This medicine reduces the number of flare ups of COPD symptoms.

This medicine contains two active substances.

- Salmeterol: a long-acting substance that widens the airways
- Fluticasone: a corticosteroid which reduces swelling and inflammation in the lungs

2. What you need to know before you use Roadasan Forspiro

Do not use Roadasan Forspiro

- if you are **allergic** to salmeterol, fluticasone or to the other ingredient of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Roadasan Forspiro if you have:

- heart disease, including an irregular or fast heartbeat
- overactive thyroid gland
- high blood pressure
- diabetes mellitus (Roadasan Forspiro may increase your blood sugar)
- low potassium in your blood
- tuberculosis (TB) now or in the past or other lung infections

Contact your doctor if you experience blurred vision or other visual disturbances.

Roadasan Forspiro prevents the onset of breathlessness and wheezing. Please note that it does not work when you are already breathless or wheezy.

If such a **breathlessness attack** occurs, you need to use a medicine which quickly widens the airways, such as salbutamol.

Inform your doctor immediately if your asthma or breathing gets worse. You may find that:

- you feel more wheezy
- your chest feels tight more often
- you need to use more of your fast acting airway widening inhaler

Continue to use Roadasan Forspiro if any of these happen, but do not increase the number of inhalations. Your chest condition may be getting worse and you could become seriously ill.

Talk to your doctor as you may need additional treatment.

Children and adolescents

Roadasan Forspiro should not be used in children and adolescents less than 18 years of age.

Other medicines and Roadasan Forspiro

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The following medicines can influence or be influenced by Roadasan Forspiro:

- medicines to treat high blood pressure, heart or other illnesses, with active substance names ending with “olol” (beta-blockers), such as atenolol, propranolol and sotalol
- medicines to treat viruses including some medicines for HIV, such as ritonavir or cobicistat; Your doctor may wish to monitor you carefully if you are taking these medicines.
- medicines to treat infections, such as ketoconazole, itraconazole and erythromycin
- corticosteroids taken by the mouth or injected: medicines to treat inflammation or prevent organ transplant rejection
- diuretics, also known as ‘water tablets’ used to treat high blood pressure
- other bronchodilators (such as salbutamol)
- xanthine medicines. These are often used to treat asthma.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will assess whether you can take Roadasan Forspiro during this time.

Driving and using machines

Roadasan Forspiro is unlikely to impair your ability to drive or operate machinery.

Roadasan Forspiro contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

3. How to use Roadasan Forspiro

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- **Asthma**

The recommended dose **for adults** is:

One inhalation twice daily

Your doctor will want to regularly check your asthma symptoms.

- **Chronic obstructive pulmonary disease**

The recommended dose **for adults** is:

One inhalation twice daily

If your symptoms become controlled using Roadasan Forspiro twice daily, your doctor may reduce your dose to once daily:

- once at night if you have night-time symptoms
- once in the morning if you have daytime symptoms

Method of use

Use Roadasan Forspiro every day as prescribed by your doctor, preferably **right before mealtimes** in the morning and/or in the evening.

After use, rinse your mouth with water.

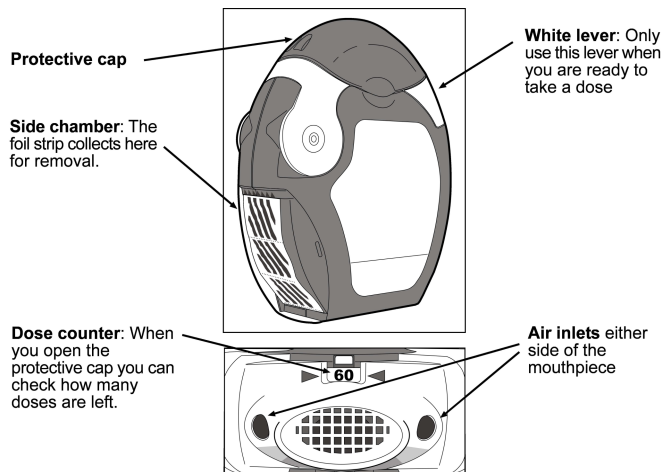
Not using Roadasan Forspiro properly or as prescribed may worsen your breathing difficulties. For optimal therapy, you must use Roadasan Forspiro daily, even if you don't have any symptoms.

Instructions for use

Your doctor, nurse or pharmacist should demonstrate how to use the inhaler and should check your use regularly.

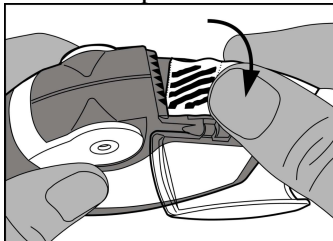
The inhaler contains 60 doses of powder medication in a coiled strip of foil. It has a dose counter which shows you how many doses you have remaining counting down from 60 to 0. When you have reached the last 10 doses the numbers will be on a red background.

The inhaler is not refillable – please dispose of the inhaler when it is empty and replace it with a new one.



Before using the inhaler

- Open the transparent side chamber door.
- Remove the foil strip from the side chamber by carefully tearing away the full length of strip against the 'teeth' of the side chamber as shown below. **Do not pull or tug** on the strip.



- Close the side chamber door and dispose of the used strip.

Important:

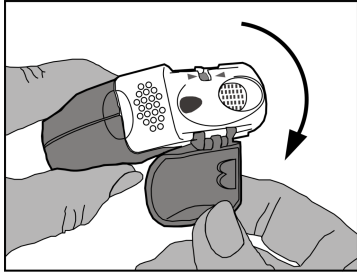
As you use the inhaler the side chamber will gradually fill up with used strip. The foil strips with **black bars don't contain medication**. Eventually the numbered sections of the strip will appear in the side chamber.

Do not let more than 2 sections of foil strip build up in the side chamber as they may cause the inhaler to jam. Tear the strip away carefully as shown above, and dispose of it safely.

Using the inhaler

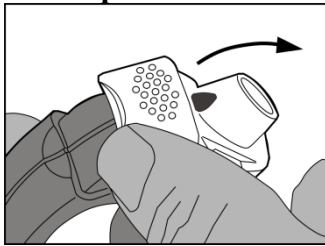
Hold the inhaler in your hands as seen in the pictures.

1. Open

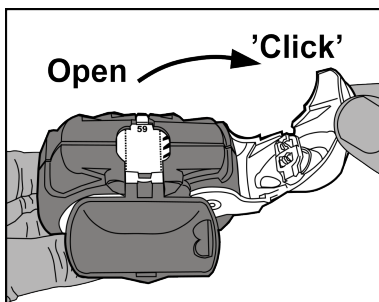


- **Open** the protective **cap downwards** to reveal the mouthpiece.
- Check the dose counter to see how many doses are left.

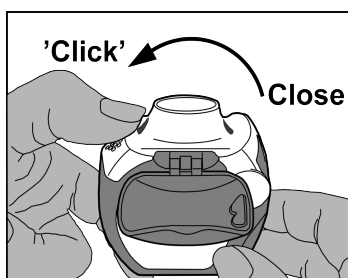
2. Prepare the dose



- **Lift up** the edge of the **white lever**. Make sure the side chamber is closed.
Remember: Only operate the white lever when you are ready to inhale a dose of your medication. If you play with the white lever, you will waste doses.



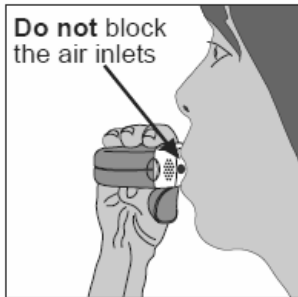
- **Open:** Move the **white lever fully over** as far as it will go and **until it clicks**. This action moves a new dose into position with the number at the top.



- **Close:** Afterwards **close** the **white lever fully** so that it **clicks** back into its original position. The inhaler is now ready for immediate use.

3. Inhale

- Away from the inhaler mouthpiece, breathe out as much as is comfortable. **Never breathe directly into** the inhaler as this could affect the dose.
- Hold the inhaler level with the **protective cap pointing downwards**.
- Close your lips firmly around the mouthpiece.
- **Breathe** in steadily and **deeply** through the inhaler, not through your nose.



- Remove the inhaler from your mouth and **hold your breath for 5-10 seconds** or as long as you can without causing discomfort.
- Afterwards, breathe out slowly, **but not into the inhaler**.
- Close the protective cap over the mouthpiece.
- Rinse your mouth with water and spit it out. This may help to prevent you from getting fungal infection in the mouth and becoming hoarse.

Cleaning

- Wipe the outside of the mouthpiece with a clean, dry tissue if necessary.
- Do not attempt to take the inhaler apart to clean it or for any other purpose!
- Do not use water or wet wipes to clean the inhaler parts as dampness can affect the dose!
- Never insert a pin or other sharp objects into the mouthpiece, or any other part, as this could damage the inhaler!

If you use more Roadasan Forspiro than you should

Contact your doctor or pharmacist.

Overdose symptoms are:

- dizziness
- headache
- rapid heart beat
- muscle weakness
- aching joints
- feeling shaky

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

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you forget to use Roadasan Forspiro

Do not take a double dose to make up for a forgotten dose. Use your next dose when it is due.

If you stop using Roadasan Forspiro

Do not stop or suddenly reduce your dose of Roadasan Forspiro without your doctor's permission as this could cause your breathing problems to worsen and very rarely side effects could occur. These include:

- stomach pain
- tiredness and loss of appetite, feeling sick
- sickness and diarrhoea
- weight loss
- headache or drowsiness
- low levels of sugar in your blood
- low blood pressure and seizures (fits)

Very rarely, if you get an infection or at times of extreme stress (such as from fever, trauma, infection, after a serious accident or if you have surgery), you may get similar side effects. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids (like prednisolone).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Roadasan Forspiro. You may be very wheezy and cough or be short of breath. You may also notice itching, a rash (hives) and swelling (usually of the face, lips, tongue, or throat), or you may suddenly feel your heart beating very fast or you feel faint and light headed (which may lead to collapse or loss of consciousness).. **If you get any of these effects or if they happen suddenly after using Roadasan Forspiro, tell your doctor straight away.** Allergic reactions to Roadasan Forspiro are uncommon (they may affect up to 1 in 100 people).

Other side effects can occur with the following frequencies:

Very Common, may affect more than 1 in 10 people

- headache
This usually gets better as treatment continues.
- increased number of colds in patients with COPD

Common, may affect up to 1 in 10 people

- thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue, hoarse voice and throat irritation.

Rinsing your mouth out with water and spitting it out immediately and/or brushing your teeth after taking each dose of your medicine may help. Your doctor may prescribe an anti-fungal medication to treat the thrush.

- aching, swollen joints and muscle pain
- muscle cramps

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD)

- Pneumonia (infection of the lung)
Tell your doctor if you have any of the following while taking Roadasan Forspiro, they could be symptoms of a lung infection:
 - increase in mucous production
 - change in mucous colour
 - fever
 - chills
 - increased cough
 - increased breathing difficulties
- bruising and fractures throughout the body
- inflammation of the sinuses
- low potassium level in the blood (you may get an uneven heartbeat, muscle weakness and/or cramp)

Uncommon, may affect up to 1 in 100 people

- very fast heartbeat (tachycardia)
- feeling shaky and a fast or uneven heartbeat (palpitation)
This is usually harmless and decreases during therapy.
- feeling worried
This effect mainly occurs in children.
- increased blood sugar level
If you have diabetes, more frequent blood sugar monitoring and possible adjustment of your diabetic medicines may be required.
- disturbed sleep
- chest pain
- clouding of the eye lens (cataract)
- allergic skin rash

Rare, may affect up to 1 in 1,000 people

- **breathing difficulties** or **wheezing** that **gets worse** straight after using Roadasan Forspiro.
Stop using your Roadasan Forspiro and use your fast-acting airway widening inhaler to help your breathing. **Tell your doctor straight away.**
- abnormal production of certain hormones, particularly when using this medicine in high doses over a long time
Signs are:
 - slowing of growth in children and adolescents
 - thinning of the bones

- increased eye pressure (glaucoma)
- weight gain
- rounded, moon shaped face (Cushing's Syndrome).

Your doctor will check you regularly for any of these side effects, ensuring you are on the lowest dose possible.

- behavioural changes, such as being unusually active and irritable
These effects mainly occur in children.
- irregular heartbeat or heart gives an extra beat
Tell your doctor, but do not stop using Roadasan Forspiro unless told to do so.
- fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing

Frequency **not known**, but may also occur

- depression or aggression
These effects mainly occur in children.
- blurred vision.

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 directly **via the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Roadasan Forspiro

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

Do not store above 25 °C.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Roadasan Forspiro contains

Roadasan Forspiro 50/500 microgram inhalation powder, predispensed:

- The active substances are salmeterol and fluticasone. Each metered dose of Roadasan Forspiro provides 50 micrograms of salmeterol (as salmeterol xinafoate) and 500 micrograms of fluticasone propionate. Corresponding with a delivered dose of:
- 45 micrograms of Salmeterol (as salmeterol xinafoate) and 465 micrograms of fluticasone propionate

- The other ingredient is lactose monohydrate.

What Roadasan Forspiro looks like and contents of the pack

- In the purple plastic dry-powder inhalation device, 60 doses of powder blend are contained in an aluminium blister.
- Each dose is pre-dispensed.

Pack sizes: 1, 2, 3 or 10 devices containing 60 doses

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

This leaflet was last revised in 20 February 2018.

[To be completed nationally]