

PACKAGE LEAFLET: INFORMATION FOR THE USER

RESPIRO

25microgram/250microgram per metered dose pressurized inhalation, suspension

SALMETEROL/FLUTICASONE PROPIONATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What RESPIRO is and what it is used for
2. Before you take RESPIRO
3. How to take RESPIRO
4. Possible side effects
5. How to store RESPIRO

1. WHAT RESPIRO IS AND WHAT IS IT USED FOR

RESPIRO contains two medicines, salmeterol and fluticasone propionate. Salmeterol is a long acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours. Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

The doctor has prescribed this medicine to help prevent breathing problems such as asthma.

You must use RESPIRO every day as directed by your doctor. This will make sure that it works properly in controlling your asthma and COPD (chronic obstructive pulmonary disease) attacks. RESPIRO helps to stop breathlessness and wheeziness coming on. However RESPIRO should not be used to relieve a sudden attack of breathlessness or wheezing. If this happens you need to use a fast-acting 'reliever' ('rescue') inhaler, such as salbutamol.

2. BEFORE YOU TAKE RESPIRO

Do not take RESPIRO

- If you are allergic to salmeterol, fluticasone propionate or to the other ingredient norflurane (HFA 134a).

Take special care with RESPIRO

Talk to your doctor before using RESPIRO if you have:

- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (RESPIRO may increase your blood sugar)
- Low potassium in your blood
- Tuberculosis (TB) now, or in the past, or other lung infections

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because RESPIRO may not be suitable to be taken with some other medicines.

Tell your doctor if you are taking the following medicines, before starting to use RESPIRO:

- β blockers (such as atenolol, propranolol and sotalol). β blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ritonavir, ketoconazole, itraconazole and erythromycin). Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body. This can increase your risk of experiencing side effects with RESPIRO, including irregular heartbeats, or may make side effects worse.
- Corticosteroids (by mouth or by injection). If you have had these medicines recently, this might increase the risk of this medicine affecting your adrenal gland.

Taking RESPIRO with food and drink

There are no interaction between RESPIRO and food and drink during its administration.

Pregnancy and breastfeeding

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.

Driving and using machines

RESPIRO is not likely to affect your ability to drive or use machines.

3. HOW TO TAKE RESPIRO

Use your RESPIRO every day, until your doctor advises you to stop. Do not take more than the recommended dose. Check with your doctor or pharmacist if you are not sure.

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

The recommended dose for adults and children over 12 years:

- RESPIRO 25/250 - 2 puffs twice a day

RESPIRO 25/250 is not recommended for use in children below 12 years of age.

Your symptoms may become well controlled using RESPIRO twice a day. If so, your doctor may decide to reduce your dose to once a day. The dose may change to:

- once at night - if you have **night-time** symptoms

- once in the morning - if you have **daytime** symptoms.

It is very important to follow your doctor's instructions on how many puffs to take and how often to take your medicine.

If you are using RESPIRO for asthma, your doctor will want to regularly check your symptoms.

If your asthma or breathing gets worse tell your doctor straight away. You may find that you feel wheezier, your chest feels tight more often or you may need to use more of your fast-acting 'reliever' medicine. If any of these happen, you should continue to take RESPIRO but do not increase the number of puffs you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

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 RESPIRO properly or as prescribed may mean that it will not help your asthma as it should.

The medicine is in the container under pressure with a plastic mouthpiece.

At the front side of RESPIRO, there is a counter that tells you how many doses of medication are left in the container. Each time you press the container, the dose of the medicine will be released and counter will count down a bit. Counter measures within the interval of 20 doses. Be careful not to drop the inhaler as this may cause the counter to start to count down.

Testing the inhaler:

1. When you use the inhaler for the first time, make sure it works. Remove the cap from the mouthpiece gently pressing on the lid with your thumb and forefinger and pull forward.
2. In order to make sure it works, shake it well, point the mouthpiece away from you and press the container to dose out into the air. If you have not used the inhaler for a week or more, release at least two doses into the air. It is very important to breathe as slowly as possible before using the inhaler.

The use of the inhaler:

1. While using inhaler stand or sit upright.
2. Remove the cap from the mouthpiece (as shown in the first picture). Check inside and out that the mouthpiece is clean and that whether it contains foreign objects.
3. Shake the inhaler 4-5 times to ensure that the released particles have been removed and that the contents of the inhaler are evenly mixed
4. Hold the inhaler upright with your thumb on the bottom below the mouthpiece. Exhale all the way to the borders of discomfort.
5. Place the mouthpiece into your mouth between your teeth. The lips should be closed firmly around the mouthpiece, and do not bite it.
6. Breathe through your mouth. Shortly after you start breathing, press the upper part of the inhaler to release the dose. Do this while you are still breathing steadily and deeply.
7. Hold your breath, remove the inhaler from your mouth and remove your finger from the top of the inhaler. Hold your breath for a few seconds or until you experience discomfort.
8. Wait about half a minute between taking each dose and then repeat steps 3 through 7.
9. The mouth should be rinsed with water, which should be spat out afterwards. This may help to prevent getting fungal infections in the mouth and becoming hoarse.
10. Immediately after use, place the cap back onto the mouthpiece to protect it from dust. The lid of the mouthpiece will make a "click" when it is set correctly. If it does not make a "click", it is necessary to turn the lid of the mouthpiece on the other side and try again. Do not use too much force while doing this.

Counter on the container turns red when you have 40 doses of the medicine. Counter turns completely red when you have 20 doses of the medicine, which indicates that the amount of the medicine in the container is low. In this case, please contact your doctor. When the counter reaches 0, do not use the inhaler because the

remaining amount of medicine in the inhaler does not contain an adequate dose for you. Do not change the number on the counter and do not try to remove the counter.

Cleaning:

Inhaler should be cleaned at least once a week, to prevent the blockade.

To clean your inhaler:

- Remove the cap from the mouthpiece.
- The metal container must not be separated from the plastic case.
- Inside and outside of the mouthpiece and the plastic casing should be wiped with a dry cloth or fabric.
- Return the lid of the mouthpiece in the correct position. Do not use excessive force as the cover will click when it locks into place properly.

The metal container must not be put into the water.

If you take more RESPIRO than you should

It is important to use the inhaler as instructed. If you accidentally take a larger dose than recommended, talk to your doctor or pharmacist. You may notice your heart beating faster than usual and that you feel shaky. You may also have dizziness, a headache, muscle weakness and aching joints.

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 RESPIRO may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to take RESPIRO

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop using RESPIRO

It is very important that you take your RESPIRO every day as directed. **Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of RESPIRO.** This could make your breathing worse.

In addition, if you suddenly stop taking RESPIRO or reduce your dose of RESPIRO this may (very rarely) cause you to have problems with your adrenal gland (adrenal insufficiency) which sometimes causes side effects.

These side effects may include any of the following:

- Stomach pain
- Tiredness and loss of appetite, feeling sick
- Sickness and diarrhea
- Weight loss
- Headache or drowsiness
- Low levels of sugar in your blood
- Low blood pressure and seizures (fits)

When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse and you may have any of the side effects listed above.

If you get any side effects, talk to your doctor or pharmacist. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids in tablet form (such as prednisolone).

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest dose of RESPIRO to control your asthma.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using RESPIRO. 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 that your heart is 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 RESPIRO, stop using RESPIRO and tell your doctor straight away.** Allergic reactions to RESPIRO are uncommon (they affect less than 1 person in 100).

Other side effects are listed below:

Very Common (affects more than 1 person in 10)

- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.

Common (affects less than 1 person in 10)

- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue and 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 and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increase in sputum production, change in sputum color, fever, chills, increased cough, and increased breathing problems.
- Throat irritation. Rinsing your mouth out with water and spitting it out immediately after taking each puff may help.
- Bruising and fractures.
- Inflammation of sinuses (a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache)
- A reduction in the amount of potassium in the blood (you may get an uneven heartbeat, muscle weakness, cramp).

Uncommon (affects less than 1 person in 100)

- Increases in the amount of sugar (glucose) in your blood (hyperglycaemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required.
- Cataract (cloudy lens in the eye).
- Very fast heartbeat (tachycardia).
- Feeling shaky (tremor) and fast or uneven heart beat (palpitations) - these are usually harmless and get less as treatment continues.
- Chest pain.
- Feeling worried (this effect mainly occurs in children).
- Disturbed sleep.
- Allergic skin rash.

Rare (affects less than 1 person in 1000)

- **Breathing difficulties or wheezing that get worse straight after taking RESPIRO.** If this happens **stop using your RESPIRO inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**

- RESPIRO may affect the normal production of steroid hormones in the body, particularly if you have taken high doses for long periods of time. The effects include:

- Slowing of growth in children and adolescents
- Thinning of the bones
- Glaucoma
- Weight gain
- Rounded (moon shaped) face (Cushing's syndrome)

Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of RESPIRO to control your asthma.

- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heart beat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking RESPIRO unless the doctor tells you to stop.
- A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

Frequency not known, but may also occur:

- Depression or aggression. These effects are more likely to occur in children.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RESPIRO

Keep out of the reach and sight of children.

Do not use the eye drops after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Store in original package in order to protect from light.

Discard the bottle 28 days after opening, even if there is solution remaining.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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6. FURTHER INFORMATION

What RESPIRO contains

Each individual dose contains 25 mcg of salmeterol and 250 mcg Fluticasone propionate

Other ingredients:

Norflurane HFA 134a

What RESPIRO looks like and contents of the pack

120 doses, a metal container with a concave bottom with a metering valve, the aerosol salmeterol / fluticasone 25/250 microgram with 10.22 g of the suspension for the pressurized inhalation.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Deva Holding AS, Halkalı Merkez Mah. Basın Ekspres Cad. 34303 No: 1, Kucukcekmece / Istanbul, Turkey

Manufacturer of the medicinal product

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