

Zoreeda 25microgram/125 microgram per actuation pressurised inhalation, suspension
Zoreeda 25microgram/250microgram per actuation pressurised inhalation, suspension

salmeterol/fluticasone propionate

Read this leaflet carefully BEFORE you start taking this medicine because it contains important information for you.

- **Keep this leaflet. You may need it to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms 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 Zoreeda is and what it is used for
2. What you need to know before you use Zoreeda
3. How to use Zoreeda
4. Possible side effects
5. How to store Zoreeda
6. Contents of the pack and other information

1. WHAT ZOREEDA IS AND WHAT IT IS USED FOR

Zoreeda 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 Zoreeda every day as directed by your doctor. This will make sure that it works properly in controlling your asthma.

Zoreeda helps to stop breathlessness and wheeziness coming on. However, Zoreeda 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. You should always have your fast-acting ‘rescue’ inhaler with you.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ZOREEDA

Do not take Zoreeda:

If you are allergic (hypersensitive) to salmeterol, fluticasone propionate or to the other ingredient norflurane (HFA134a).

Warnings and precautions

Talk to your doctor before using Zoreeda if you have:

- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Zoreeda 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

Other medicines and Zoreeda

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines for asthma or any medicines obtained without a prescription. This is because Zoreeda 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 Zoreeda:

- 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 ketoconazole, itraconazole and erythromycin including some medicines for HIV treatment (such as ritonavir, cobicistat-containing products))
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 Zoreeda, 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.
- 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 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

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

3. HOW TO USE ZOREEDA

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

- Use your Zoreeda 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.
- Do not stop taking Zoreeda or reduce the dose of Zoreeda without talking to your doctor first.
- Zoreeda should be inhaled through the mouth into the lungs.

Adults

Zoreeda is indicated for use in adults 18 years of age and older only.

- Zoreeda 25microgram/125 microgram - 2 puffs twice a day
- Zoreeda 25 microgram /250 microgram - 2 puffs twice a day

Adolescents aged 13 to 17 years

Zoreeda is not indicated for the management of asthma in adolescents 13 to 17 years of age. No data are available on the use of Zoreeda in this age group.

Children 12 years of age and younger:

Zoreeda is not indicated for the management of asthma in children 12 years of age and younger. No data are available on the use of Zoreeda in this age group. Neither of the two strengths of

Zoreeda can be used in the management of asthma in children as the dose of the corticosteroid (fluticasone propionate) in both strengths of Zoreeda is too high for use in this young age group.

If your asthma or breathing gets worse tell your doctor straight away. You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast-acting ‘reliever’ inhaler. If any of these happen, you should continue to take Zoreeda 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 straightaway as you may need additional treatment.

Your doctor will assess your asthma symptoms regularly to make sure you are taking the correct dose of Zoreeda and will reduce your dose to the lowest dose required to control your symptoms.

However Zoreeda is only available in two strengths, 25/125micrograms and 25/250micrograms. If your doctor feels that you need a lower dose of your inhaler than is available with Zoreeda, your doctor will change you to an alternative combination product containing the same two medicines but in a lower strength. This is currently available on the market.

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

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 Zoreeda properly or as prescribed may mean that it will not help your asthma as it should.
- The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.
- There is a dose indicator on the front of the Inhaler. The dose indicator will show the number of doses left in the canister through a window in the plastic actuator. As you use the inhaler the dose indicator will typically rotate during every five to seven puffs towards the next decreasing number. The dose indicator will show the approximate number of puffs remaining in the inhaler. You should get a replacement when the indicator shows the number ‘40’ and the color on the dose indicator will change from green to red. Stop using the Inhaler when the indicator shows ‘0’ as any puffs left in the device may not be enough to give you a full dose.
- Take care not to drop the Inhaler as this may cause the 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 side with your thumb and forefinger and pull apart.

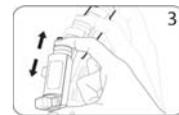


2. To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release four puffs into the air. The dose indicator will show the number ‘120’ indicating the number of puffs in the inhaler. If you have not used your inhaler for a week or more, shake well and release two puffs of medicine into the air.

Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1. Stand or sit upright when using your inhaler.
2. Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of loose 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.



4. Hold the inhaler upright with your thumb on the base below the mouthpiece. Breathe out as far as is comfortable.



5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.



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.



7. Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. 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 7.
9. Afterwards, rinse your mouth with water and spit it out, and/or brush your teeth. This may help to stop you getting thrush and becoming 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 4, 5, 6 and 7. 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 should ensure that patients prescribed Zoreeda use correct inhalation technique, as described above.

Spacer device

If you find it difficult to use the inhaler, either your doctor or other healthcare provider may recommend using a spacer device such as the Volumatic® or AeroChamber Plus® with your inhaler. Limited data available from a study shows that the spacer to be washed and dried prior to use.

Your doctor, nurse, pharmacist or other healthcare provider should show you how to use the spacer device with your inhaler and how to wash and care for your spacer device correctly and will answer any questions you may have.

However, a spacer device is recommended only for use with the Zoreeda 25microgram/250 microgram inhaler (the high strength inhaler): a spacer device is NOT recommended for use with Zoreeda 25microgram/125 microgram Inhaler (the lower strength inhaler). If you need to use a spacer device with this lower strength inhaler, you will have to change to an alternative inhaler containing the same medicines, that is salmeterol 25microgram and fluticasone propionate 125 microgram, licensed for use with a spacer device.

If you have previously used an alternative product and spacing device and are then transferred to these new fixed-dose combination inhalers with or without a spacing device, re-titration of your dose to the lowest effective dose should always be carried out.

Patients should continue to use the same make of spacer device, either the Volumatic spacer device or the AeroChamber Plus spacer device, as switching between spacer devices can result in changes in the dose delivered to the lungs.

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 or nurse

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.

People with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece.

You should get a replacement when the indicator shows the number '40' and the color on the dose indicator will change from green to red. Stop using the Inhaler when the indicator shows '0' as any puffs left in the device may not be enough to give you a full dose. Never try to alter the numbers on the indicator or detach the indicator from the actuator. The indicator cannot be reset and is permanently attached to the actuator.

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 in water

If you use more Zoreeda 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 Zoreeda may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use Zoreeda

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 Zoreeda

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

In addition, if you suddenly stop taking Zoreeda or reduce your dose of Zoreeda 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 diarrhoea
- 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.

<p>4. POSSIBLE SIDE EFFECTS</p>
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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 Zoreeda to control your asthma.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Zoreeda. You may need to use your fast-acting ‘reliever’ inhaler to help your breathing. 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 Zoreeda, stop using Zoreeda and tell your doctor straight away. Allergic reactions to Zoreeda 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 chronic obstructive pulmonary disease (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 medicine to treat the thrush.
- Aching, swollen joints and muscle pain.
- Muscle cramps.

The following side effects have also been reported in patients with COPD:

- Pneumonia and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increase in sputum production, change in sputum colour, fever, chills, increased cough, 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 Zoreeda.** If this happens stop using your Zoreeda. Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**
- Zoreeda 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 Zoreeda to control your asthma.

- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heart beat or your heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking Zoreeda unless the doctor tells you to stop.
- Thrush, a fungal infection in the oesophagus (gullet, food canal), 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.
- 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

HPRA Pharmacovigilance,

Earlsfort Terrace,

IRL- Dublin 2,

Tel: + 353 1 6764971;

Fax: + 353 1 6762517;

Website: www.hpra.ie,

E-mail: medsafety@hpra.ie

5. HOW TO STORE ZOREEDA

- **Keep this medicine out of the sight and reach of children.**
- 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 store above 25°C.
- The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C, protect from direct sunlight. Do not pierce or burn the canister even when empty.
- As with most inhaled medicinal products in pressurised canisters, the beneficial effects of your medicine may decrease when the canister is cold.

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 Zoreeda contains

- Each metered dose contains 25 micrograms of salmeterol (as salmeterol xinafoate) and 125 or 250 micrograms of fluticasone propionate. The other ingredient is propellant: norflurane (HFA 134a).

What Zoreeda looks like and contents of the pack

- Aluminium canister with a suitable metering valve and a polypropylene actuator with dust cap (pink (25microgram/125 microgram) or rubine red (25microgram/250 microgram)) and with a dose indicator attached to the actuator, in a sealed pouch containing desiccant.
- Each canister is filled to deliver 120 doses.

Pack sizes:

1, 2 (bundled package 2x1) or 3 (bundled package 3x1) canisters containing 120 doses.
10 (bundled package 10x1) canisters containing 120 doses -hospital/pharmacy use only.

Marketing Authorisation Holder:

Cipla Europe NV
De Keyserlei 58-60, Box-19,
2018 Antwerp,
Belgium

Manufacturer:

Cipla (EU) Limited, Dixcart House, Addlestone Road,
Bourne Business Park, Addlestone,
Surrey, KT15 2LE,
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Cipla Europe NV,
De Keyserlei 58-60, Box-19,
2018 Antwerp,
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Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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