

PACKAGE LEAFLET

Package leaflet: Information for the patient

Novolizer Formoterol ® 6 micrograms /dose inhalation powder Formoterol

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 Novolizer Formoterol 6 micrograms is and what it is used for
2. What you need to know before you use Novolizer Formoterol 6 micrograms
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1. WHAT NOVOLIZER FORMOTEROL 6 MICROGRAMS IS AND WHAT IT IS USED FOR

Novolizer Formoterol is a powder for inhalation containing formoterol. Formoterol belongs to a group of medicines known as long-acting beta-agonists. These medicines relax certain muscles, for example, they open up the airways of your lungs.

Novolizer Formoterol 6 micrograms gives a long-lasting relief (up to 12 hours) of symptoms such as wheezing, shortness of breath and coughing in patients with **asthma** already receiving inhaled glucocorticosteroids. It makes breathing easier by relaxing muscle spasms in the air passages of the lungs. Regular use of Novolizer Formoterol 6 micrograms with inhaled glucocorticosteroids will help to prevent breathing problems.

Novolizer Formoterol 6 micrograms is also used for the relief of symptoms such as wheezing, shortness of breath and coughing in patients with **chronic obstructive pulmonary disease (COPD)**.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NOVOLIZER FORMOTEROL 6 MICROGRAMS

Do NOT use Novolizer Formoterol 6 micrograms if you are allergic (hypersensitive) to formoterol or the other ingredient of this medicine (listed in section 6).

Warning and precautions

Talk to your doctor or pharmacist before using Novolizer Formoterol 6 micrograms.

Novolizer Formoterol 6 micrograms should **not be used (and is not sufficient) as the first treatment** for asthma.

Novolizer Formoterol 6 micrograms should not be used to treat an acute asthma attack. In this case you should take your short-acting bronchodilator (e.g. salbutamol).

If you are an asthmatic patient, you should **also receive treatment with glucocorticosteroids** in order to reach optimal treatment of bronchial inflammation.

It is important that you continue taking your anti-inflammatory therapy (glucocorticosteroid). You should not decrease the dose of anti-inflammatory therapy (glucocorticosteroid) following the introduction of formoterol without a medical advice even when symptoms improve.

If you need your medication for the prevention of exercise-induced asthma more frequently than you usually take it, this can be a sign that your asthma control isn't good enough. In this case you should contact your doctor for a reassessment of the asthma therapy.

Take special care and talk to your doctor before using Novolizer Formoterol 6 micrograms if you have

- any heart disease,
- blood pressure problems,
- diabetes,
- an overactive thyroid gland or
- problems with adrenal glands.

As with other inhalation therapy there is a risk of paradoxical bronchospasm (immediate increase in wheezing and shortness of breath) immediately after using the inhaler. If this occurs you should talk immediately with your doctor.

Should your symptoms continue or worsen or the number of doses of formoterol you need to take to control symptoms increases, this usually indicates a worsening of disease; in these cases you should contact your doctor in order to reassess your treatment.

Children

This medicine is not recommended for use in children below age of 6.

Other medicines and Novolizer Formoterol 6 micrograms

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, this applies for:

- other beta-agonists (e.g. salbutamol, salmeterol) or ephedrine
- xanthine derivatives (e.g. theophylline)
- steroid medicines (e.g. prednisolone)
- diuretics or water tablets (e.g., furosemide)
- digoxin
- antihistamines (e.g. terfenadine, astemizole)
- medicines for a rapid or irregular heart beat (e.g. quinidine)
- phenothiazines (e.g. chlorpromazine) used to treat mental illness or severe nausea and vomiting
- antibiotics (e.g. erythromycin)
- tricyclic antidepressants (e.g. amitriptyline) or monoamine oxidase inhibitors (phenelzine)
- hormones (e.g. L-thyroxine, oxytocin)
- beta-blockers for high blood pressure or angina (taken by mouth as e.g. atenolol, metoprolol or as eye drops e.g. timolol)

- Some general anaesthetics may interact with formoterol to cause heart problems and decrease of blood pressure. Therefore, if you are having an **operation**, advise hospital staff that you are taking Novolizer Formoterol 6 micrograms.
- As with other medicines of this type, if Formoterol is taken with **alcohol**, or with medicines for **Parkinson's disease** or **thyroid problems** you may experience an increase in heart rate (pulse).

Novolizer Formoterol 6 micrograms with food, drink and alcohol

You should avoid drinking of alcohol because you may experience an increase in heart rate (pulse).

Food and other drinks are not known to alter the effectiveness of Novolizer Formoterol 6 micrograms.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Formoterol should only be used during pregnancy (particularly during the first three months and at the end of the pregnancy and during labour), after special consideration.

It is not known whether formoterol passes into human breast milk. Therefore, administration of Novolizer Formoterol 6 micrograms during breastfeeding should only be considered if the expected benefit to you is greater than any possible risk to the child.

Driving and using machines

Novolizer Formoterol 6 micrograms does not affect the ability to drive or use machines.

Novolizer Formoterol 6 micrograms contains milk sugar (lactose).

Normally, the content of lactose in a single dose does not cause any problems in people with lactose intolerance. Milk sugar (lactose) may contain small amounts of milk protein.

3. HOW TO USE NOVOLIZER FORMOTEROL 6 MICROGRAMS

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If the person taking the medicine is a child, he or she should be shown how to use the inhaler correctly and should only use the inhaler with the help of an adult.

The recommended dose is:

Asthma

Adults (including older people) and adolescents over 12 years of age

The usual dose is 2 puffs in the morning and 2 puffs again at night. For more severe asthma your doctor may prescribe 4 puffs twice daily.

The maximum daily dose is 8 puffs (4 puffs inhaled twice daily).

Use in children 6 years and older

The usual dose is 2 puffs in the morning and 2 puffs again at night. For more severe asthma your doctor may prescribe 4 puffs twice daily.

The maximum daily dose is 8 puffs (4 puffs inhaled twice daily).

The regular daily dose should not exceed 4 puffs, however, occasionally up to a maximum of 8 puffs may be allowed within a 24-hours period.

Use in children below 6 years of age

Novolizer Formoterol is not recommended for use in children under the age of 6 years as insufficient experience is available in this age group.

COPD (chronic obstructive pulmonary disease)

Adults (including older people) and adolescents over 12 years of age

The usual dose is 2 puffs in the morning and 2 puffs again at night.

The daily dose for regular use should not exceed 4 puffs.

If necessary, additional puffs above those prescribed for regular therapy may be used for relief of symptoms, up to a maximum total daily dose of 8 puffs. More than 4 puffs should not be taken on any single occasion.

Method of Administration

For inhalation use.

Inhale as shown in the 'Instructions for Use' on the back of this leaflet.

If you use more Novolizer Formoterol 6 micrograms than you should

The symptoms of an overdose correspond to the side effects. These are for example: trembling, headache, palpitations, nausea and vomiting.

If any of these reactions occur you should contact your doctor immediately.

If you forget to use Novolizer Formoterol 6 micrograms

Take your dose as soon as you remember, if it is nearly time for the next dose just take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop using Novolizer Formoterol 6 micrograms

Do not stop or reduce the dose of Novolizer Formoterol 6 micrograms or any other medicine for your breathing just because you feel better, without talking to your doctor first. It is very important to use these medicines regularly.

If you feel sick or very shaky or if you have an unusually fast heart beat, your Novolizer Formoterol dose may be too high. Tell your doctor as soon as possible.

Once your symptoms are controlled your doctor may consider to step down the dose of Novolizer Formoterol gradually to adjust your treatment to the lowest effective dose.

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.

Possible side effects are listed below according to their frequency. If you are not sure what the side effects below are, ask your doctor to explain them to you.

Most important side effects

As with all inhalers it is possible for the powder to make you **wheezy** immediately after inhalation. This occurs rarely (may affect up to 1 in 1,000 people).

Rarely an allergic reaction may result in a condition known as angioneurotic oedema which is a **swelling of the face, lips, eyes and throat**. If any of these allergic reactions occur you must stop taking Novolizer Formoterol immediately and contact your doctor.

Very rarely (may affect up to 1 in 10,000 people) **severe chest pain** (angina pectoris) can occur.

List of all other side effects

Common side effects (may affect up to 1 in 10 people):

Headache, trembling and palpitations.

Uncommon side effects (may affect up to 1 in 100 people):

Agitation, restlessness, difficulty sleeping, muscle cramps and irritation of the throat.

Rare side effects (may affect up to 1 in 1,000 people):

Rapid or unusual heart beat, nausea (feeling sick), changes in potassium levels that may cause muscle weakness, nervousness and wheeziness. Allergic reactions such as skin reactions like exanthema, urticaria and pruritus which result in transient rash, patchy swelling, redness and itching.

Very rare side effects (may affect up to 1 in 10,000 people):

Prolongation of QTc-interval which could increase the risk of severe heart rhythm disorder in sensitive patients, hyperglycaemia (increase in blood glucose), unusual taste, dizziness, and changes in blood pressure.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NOVOLIZER FORMOTEROL 6 MICROGRAMS

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, the carton and the cartridge container. The expiry date refers to the last day of that month.

Storage conditions

Store the cartridge in the original package until required for use.

After opening the cartridge container and inserting into the Novolizer device, store Novolizer Formoterol 6 micrograms in a dry place protected from moisture and below 25 °C.

Information concerning in-use shelf-life

Exchange the cartridge **6 months** after first opening.

Do not use the powder inhaler for more than a year.

Note: The Novolizer device should be replaced after 2000 inhalations. Therefore, a maximum of 33 cartridges containing 60 single doses should be used with this device (within a single year).

The Novolizer should be cleaned at regular intervals, but at least every time the cartridge is changed. Instructions on how to clean the device can be found in the instructions for use on the back of this leaflet.

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 Novolizer Formoterol 6 micrograms contains

Novolizer Formoterol 6 micrograms is a dry powder for inhalation. The active substance is formoterol. One puff contains 4.18 micrograms Formoterol (as fumarate dihydrate).

The other ingredient is lactose monohydrate (milk sugar). Novolizer Formoterol 6 micrograms contains 5.744 mg of lactose per puff.

What Novolizer Formoterol 6 micrograms looks like and contents of the pack

Novolizer Formoterol 6 micrograms, inhalation powder, contains a white powder in a cartridge and is available in the following packs:

Original sales packs:

- 1 powder inhaler and 1 cartridge with at least 60 puffs
- 1 powder inhaler and 2 cartridges with at least 60 puffs each

Refill packs:

- 1 cartridge with at least 60 puffs
- 2 cartridges with at least 60 puffs each
- 3 cartridges with at least 60 puffs each

Not all pack sizes may be marketed.

Marketing Authorization Holder

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoye Industrial Estate,
Dublin 13,
Ireland

Manufacturer:

VEMEDIA Manufacturing B.V.
Verrijn Stuartweg 60,
NL-1112 AX Diemen,
The Netherlands

alternative:

MEDA Manufacturing GmbH
Neurather Ring 1
D-51063 Cologne
Tel: (+49)-221-6472-0
Fax: (+49)-221-6472-696

alternative:

MEDA Pharma GmbH & Co. KG
Benzstraße 1
D-61352 Bad Homburg
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Fax: (+49)-6172-888-2740

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

Austria: Novolizer Formoterol Meda 6 Mikrogramm Pulver zur Inhalation
Belgium and Luxembourg: Novolizer Formoterol 6 microgrammes, poudre pour inhalation
Germany: Formoterol Novolizer 6 Mikrogramm, Pulver zur Inhalation
France: Asmelor Novolizer 6 microgrammes/dose, poudre pour inhalation
Ireland: Novolizer Formoterol 6 micrograms/dose inhalation powder
Italy: Formoterolo Viatris Novolizer 6 microgrammi/dose polvere per inalazione
Netherlands: Formoterol Novolizer 6 microgram, inhalatiepoeder
Portugal: Formoterol Novolizer 6 microgramas/dose, pó para inalação
Spain: Formatris Novolizer 6 microgramos/dosis, polvo para inhalación

This leaflet was last revised in November 2018

Asthma Lifestyle Advice

Asthma can be controlled in different ways. Your doctor will work with you to decide on a treatment plan which best suits your individual needs and which should help to reduce your asthma symptoms and the number of asthma attacks.

There are also ways that you can help yourself, such as:

- Try to avoid or reduce contact with things that may trigger an asthma episode, for example, animal fur, smoking (including passive smoking), moulds, pollen and house dust mites.
- If you know that exercise is a trigger for your asthma, make sure that you have followed your doctor's instructions before starting any exercise.
- Be honest with your doctor or asthma nurse about how asthma affects you day-to-day and develop with them a treatment plan that suits your particular lifestyle. Remember to take your asthma medication as your doctor has instructed.
- If you have any worries about your medication, discuss this with your local pharmacist, asthma nurse or doctor.

INSTRUCTIONS FOR USE

Novolizer[®]

(Illustration of cartridge and device with labelling:)

Cartridge

Cartridge cylinder

Sliding cap

Dosage counter

Dosage button

Control window

Protective cap

(Note: The following texts are accompanied by the corresponding illustrations.)

1. PREPARATION:

The NOVOLIZER Dry Powder Inhaler makes inhaling simple and reliable. Its straightforward use, fast cartridge replacement and simple cleaning are easy and quickly done.

Place the NOVOLIZER Dry Powder Inhaler in front of you. Lightly press together the ribbed surfaces on both sides of the cap, move the cap forwards (←) and lift off (↑).

Remove the protective aluminium foil from the cartridge cylinder and take out the new cartridge. However, this should only be done just before using the cartridge. The colour coding on the cartridge must correspond to the colour of the dosage button.

The small red disc on the bottom of the cartridge cylinder is a drying agent which should be disposed of after removal of the cartridge.

First filling:

Insert the cartridge into the NOVOLIZER Dry Powder Inhaler with the dosage counter facing the mouthpiece (↓). Do not press the dosage button while inserting the cartridge.

Refilling:

Note: The NOVOLIZER Dry Powder Inhaler should be cleaned every time the cartridge is exchanged after removal of empty cartridge.

If you have already used the NOVOLIZER Dry Powder Inhaler, first remove the empty cartridge and then insert the new one (↓). Do not press the dosage button while inserting the cartridge.

Replace the cap into the side guides from above (↓) and push down flat towards the coloured dosage button until it snaps into place (→).

The NOVOLIZER is now filled and ready for use.

You can leave the cartridge in the NOVOLIZER Dry Powder Inhaler until it has been used up or for up to 6 months after insertion. The cartridge is used up if you see a hatched "0" in the middle of the control window. Then a new cartridge has to be inserted. The cartridges may only be used in the original dry powder inhaler.

2. USAGE:

Whenever possible, sit or stand while inhaling. When using the NOVOLIZER always keep it horizontal. First remove the protective cap (←).

Completely depress the coloured dosage button. A loud double click will be heard and the colour of the control window will change from red to green. Then release the coloured button. The colour green in the control window indicates that the NOVOLIZER device is ready for use.

Exhale (but not into the NOVOLIZER Dry Powder Inhaler). Put your lips tightly around the mouthpiece, inhale the powder steadily, deeply and as rapidly as possible (to the maximum inhalation) and then hold the breath for a few seconds. During this breath a loud click should be heard, indicating correct inhalation. Then continue with normal breathing.

Check that the colour of the control window has changed back to red, also indicating a correct inhalation. Replace the protective cap on the mouthpiece – the inhalation procedure is now complete. The number in the top window indicates the number of inhalations left. The numeric scale 60-0 is shown in steps of 10. If the click sound and change of the colour did not appear, please repeat the procedure as described above.

NOTE: The coloured dosage button should only be pressed immediately before inhalation. Inadvertent overdosing is not possible with the NOVOLIZER. The click sound and the change of the colour in the control window indicate that inhalation has been performed correctly. If the colour of the control window does not change back to red, the inhalation should be repeated. If inhalation is not completed correctly after several attempts, then you should consult your doctor.

3. CLEANING:

The NOVOLIZER Dry Powder Inhaler should be cleaned at regular intervals, but at least every time the cartridge is exchanged.

Remove protective cap and mouthpiece

First remove the protective cap. Then grasp the mouthpiece and turn it briefly counter-clockwise (↶) until it becomes loose. Then remove (←).

Cleaning

Now turn the NOVOLIZER upside down. Grasp the loose dispensing slide and move it forwards (←) and upwards (↑). Any remaining powder can be removed by tapping lightly.

Clean the mouthpiece, the dispensing slide and the powder inhaler with a soft and dry lint-free cloth. Do NOT use water or detergent.

Assembly – Insert dosage slide

After cleaning insert the dosing slide by sliding down at an angle (↘) and press into position (↓).

Turn the inhaler back over.

Assembly – Fit mouthpiece and protective cap

Insert the mouthpiece with the pin into the groove on the left and turn to the right until it snaps into place. Finish by replacing the protective cap.

Notes

- The Patient Information Leaflet describes how the drug works. Please read it through carefully before using the inhaler for the first time.
- The NOVOLIZER which comes with various active substances does not use any propellants and is designed for refilling. This makes the NOVOLIZER a very environmentally friendly product.
- It is not possible to overdose with the NOVOLIZER. Even if the button is pressed several times, no more powder is available for inhalation. Only press the button when you really want to inhale. If you cannot manage to inhale correctly after several attempts, consult your doctor.

- The NOVOLIZER can be refilled using new cartridges* containing the active substance and is thus ideally suited to long-term usage (up to one year).
- Do not shake the filled NOVOLIZER.
- Please support your children in proper handling of the device.
- Make sure your NOVOLIZER is protected from moisture and heat and kept clean at all times.

* Regarding corresponding medicines, please ask your doctor.

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