PACKAGE LEAFLET: INFORMATION FOR THE USER

Novolizer Salbutamol

100 micrograms / dose Inhalation Powder
Salbutamol

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. 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 SALBUTAMOL IS AND WHAT IT IS USED FOR

Novolizer Salbutamol is indicated in adults, adolescents and children aged 6 to 12 years.

The active substance in Novolizer Salbutamol is an anti-asthmatic agent for bronchodilation (beta sympathomimetic agent).

Novolizer Salbutamol is used for
- Symptomatic treatment of conditions with associated reversible airway obstruction, e.g. asthma or chronic obstructive pulmonary disease (COPD) with a substantial component of reversibility.
- Prevention of asthma attacks induced by exercise or exposure to allergens.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NOVOLIZER SALBUTAMOL

Do not use Novolizer Salbutamol if you are allergic (hypersensitive) to Salbutamol or to lactose and/or to the milk protein contained therein.

Warnings and precautions
Talk to your doctor or pharmacist before using Novolizer Salbutamol

Take special care in using Novolizer Salbutamol,
if you are suffering from one of the following conditions

- Severe cardiac disease, in particular fresh myocardial infarction,
- Disease of the coronary vessels (coronary heart disease), a certain chronic myocardial disease (hypertrophic obstructive cardiomyopathy) and cardiac dysrhythmia with increased heart rate (tachycardiac arrhythmia)
- High blood pressure (severe and untreated hypertension)

- Abnormal dilatation of a vessel wall (aneurysm)
- Hyperfunction of the thyroid gland (hyperthyroidism)
- Diabetes mellitus which is difficult to control
- Certain disease of the adrenal medulla (phaeochromocytoma)

Tell your doctor before starting to take this medicine: If you have a history of heart disease or angina. Seek medical advice if you experience chest pain or other symptoms of worsening of your heart disease.

Care should be taken when treating acute asthma attacks or exacerbation of severe asthma as increased serum lactate levels, and rarely, lactic acidosis have been reported after the use of high doses of salbutamol. This is reversible on reducing the dose of salbutamol

Before you use the Novolizer Dry Powder Inhaler for the first time, make sure that your doctor has instructed you about correct handling of this device.

Treatment should be carried out according to the severity.
If you suffer from permanent (persistent) asthma, Salbutamol should not be used as the sole therapy. Increasing need for bronchodilating agents such as Novolizer Salbutamol is a symptom of aggravation of the disease. Medical professional must be contacted to adapt the treatment plan.
Any sudden and progressing aggravation of asthmatic symptoms may be life-threatening and therefore, a medical professional must be contacted immediately.
Any significant excessive use (in particular of the single dose recommended for acute attacks as well as of the daily dosage) may become dangerous due to its cardiac effects and therefore must be avoided. Other side effects may also be intensified.

Daily self-control in compliance with the instructions given by the treating physician is an important feature in order to assess the progression of the disease as well as the therapeutic success of the Novolizer Salbutamol and of the other medication required to treat your disease. For instance, this control is carried out by regular measuring of the forced expiration by means of a peak flow meter.

If you are a diabetic patient
Inhalation of high doses of Salbutamol can increase the blood sugar level. Therefore, blood sugar levels in diabetic patients should be monitored closely.

Other medicines and Novolizer Salbutamol

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

- Treatment with salbutamol may cause hypokalaemia (low potassium in your blood) which can be aggravated by some other drugs. These include other drugs for asthma, such as xanthine derivatives (e.g., theophylline) or steroids (e.g., prednisolone), or drugs for other conditions such as water tablets (e.g., frusemide) or digoxin. You must mention to your doctor if you are taking any of these drugs, as your doctor may want to take a blood sample to monitor your potassium levels.

- If you are taking beta-blockers (e.g. atenolol) for high blood pressure or angina, or antidepressants (e.g. moclobemide, phenelzine, amitriptyline, clomipramide or imipramine) you should also tell your doctor.

- Some general anaesthetics may interact with salbutamol to cause difficulty in breathing. Therefore, if you are having an operation, advise hospital staff that you are taking Novolizer Salbutamol.

Please, note that this information may also apply to medication used up until recently.

Pregnancy, breast-feeding and fertility
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 any medicine.
During pregnancy, in particular during the first three months as well as towards the end, Novolizer Salbutamol should be used only upon the express prescription of your treating physician and only then, if your doctor considers it to be absolutely necessary.
Inhalation of Salbutamol-containing preparations is not appropriate for the management of premature labour and should also not be used in case of threatened abortion.

Due to the fact that Salbutamol – the active substance of Novolizer Salbutamol - may pass into the breast milk, Novolizer Salbutamol is to be used during the breast-feeding period only upon the express prescription of your doctor.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.

Novolizer Salbutamol contains milk sugar (lactose), 11.42 mg of lactose monohydrate/delivered dose.
Normally, the content of lactose in a single dose does not cause any problems in persons with lactose intolerance. If you are concerned that you may have an intolerance, you must talk to your doctor.
Lactose contains small amount of milk protein.

3. HOW TO USE NOVOLIZER SALBUTAMOL

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

In order to avoid improper use, your doctor should instruct you thoroughly about correct handling of Novolizer Salbutamol. Children must use this medicinal product only when supervised by an adult and in compliance with the instructions given by the doctor.

Dosage shall be determined by the nature, severity and progress of the disease.
Should you have the impression that the effect of Novolizer Salbutamol is either too strong or too weak, discuss this with your doctor or your pharmacist.

Unless otherwise prescribed by your doctor, the following dosage is recommended for **adults (including older people and adolescents)**:
For the purpose of acute treatment in case of suddenly occurring bronchial spasm or attacks of respiratory distress, one single dose (100 micrograms) is to be inhaled.
For prevention of exercise-induced asthma or predictable allergen contact two inhalations (200 micrograms) should be taken about 10-15 minutes prior to challenge.
The maximum dose administered in any 24 hours should not exceed 8 inhalations (equivalent to 800 micrograms).
Children (aged 6 to 12 years)
For the purpose of acute treatment in case of suddenly occurring bronchial spasm or attacks of respiratory distress, one single dose (100 micrograms) is to be inhaled.
For prevention of exercise-induced asthma or predictable allergen contact one single dose (100 micrograms) should be taken about 10-15 minutes prior to challenge and another single dose, if required (total dose: 200 micrograms).
The maximum dose administered in any 24 hours should not exceed 4 inhalations (equivalent to 400 micrograms).

Children below 6 years of age

Novolizer Salbutamol is not recommended for use in children below age 6 due to insufficient data on safety and efficacy.

For all patients
In an acute attack of respiratory distress, a single inhalation usually brings about rapid relief of symptoms. If there is no noticeable improvement in symptoms 5-10 minutes after inhalation of one single dose, a second single dose may be taken. At least four hours should elapse between each dose (where one dose may be either one or two inhalations).
If a severe attack of respiratory distress is not relieved following a second single dose, or if patients are unable to trigger the Novolizer Dry Powder Inhaler device during an acute asthma attack, medical assistance should be sought immediately.

If treatment with Salbutamol is being used on an as-required basis every day for the relief of symptoms the addition of regular anti-inflammatory therapy must be considered.

When other Salbutamol inhalers are replaced by the Novolizer Salbutamol Dry Powder Inhaler the amount of Salbutamol delivered to the lung may vary between different inhalers. In these cases, the treatment plan may have to be adjusted by the doctor.

Method of Administration
For inhalation use.
Inhale as shown in the Instructions for use.

If you inhale more Novolizer Salbutamol than you should

The symptoms and signs of overdosage are similar to the side effects mentioned below. Those then will manifest themselves rapidly and probably more intensely.
Typical signs and symptoms of overdosage include:
Cardiac palpitation, irregular and/or accelerated heartbeat, severe trembling - in particular of the hands -, restlessness, sleep disturbances and chest pain.
Should these problems occur, a medical professional must be contacted immediately.

If you stop using Novolizer Salbutamol

Do not stop treatment with the Novolizer Salbutamol without talking to your doctor first because this could lead to an aggravation of the disease.

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

4. POSSIBLE SIDE EFFECTS

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

Should respiratory distress exacerbate directly after inhalation, contact a doctor immediately.

Under certain circumstances, some of the side effects mentioned above may be an acute threat to your life (like for instance life-threatening tachycardia). Therefore, a medical professional must be contacted immediately if such an event should suddenly occur and/or if it should develop an unexpected intensity.

Common (may affect up to 1 in 10 people) side effects include taste alteration (bad, unpleasant, unusual taste) and irritation in the mouth and the throat as well as burning sensation of the tongue, trembling fingers or hands (tremor), dizziness, nausea, sweating, restlessness and headache. These side effects may remit over a period of one to two weeks when treatment is continued.

In rare cases (may affect up to 1 in 1,000 people) the following may occur:

Cardiac and vascular disorders:
Accelerated heartbeat (tachycardia), cardiac arrhythmia (arrhythmia – including atrial fibrillation), additional beats of the heart muscle (extrasystoles), cardiac palpitation, effects on the blood pressure (lowering or increase)and dilatation of the blood vessels (peripheral vasodilatation).

Metabolism/electrolytes:
Lowered blood potassium level (hypokalaemia), increased blood-sugar level (hyperglycaemia), increase of insulin, free fatty acids, glycerol and ketone bodies

Nervous system & psychiatric disorders:
Abnormally increased activity (hyperactivity) (in particular in children up to 12 years of age)

Musculoskeletal system:
Muscle pain and muscle cramps

Respiratory system:
Cough and attacks of shortness of breath during/after inhalation (paradoxical bronchospasm)

In very rare cases (may affect up to 1 in 10,000 people) the following may occur:
- hypersensitivity reactions (including itching, nettle rash, skin rash, reddening of the skin, drop in blood pressure, facial and pharyngeal oedema). ***If you notice any of these reactions contact your doctor immediately.***
- decrease in the number of blood platelets (thrombocytopenia),
- inflammation of the kidney (nephritis),
- collapse,
- hyperexitability, sleeping disorders, illusion (hallucination) (in particular in children up to 12 years of age).

Very rarely, some people may experience chest pain (due to heart problems such as angina). Tell your doctor as soon as possible, but do not stop using this medicine unless told to do so.

Lactose-monohydrate contains small amounts of milk proteins and can therefore cause allergic reactions.

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 SALBUTAMOL

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.

Do not store above 30 °C. Store protected from moisture.
Store the refill cartridge in the original package until use.

Exchange the cartridge six months after first opening.
Do not use the Powder Inhaler for more than one year.

Note: The Novolizer device has been shown to function for at least 2000 single doses. Therefore a maximum of 10 cartridges containing 200 single doses can be used with this device (within a single year) prior to replacement.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Novolizer Salbutamol contains

- The active substance is salbutamol.
  Each actuation (puff) contains 100 micrograms of salbutamol (as sulphate).

- The other ingredient is Lactose monohydrate.

What Novolizer Salbutamol looks like and contents of the pack

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

Original sales packs:
1 cartridge 200 metered doses filled with not less than 2.308 g of powder packed in a plastic container sealed by aluminium foil and 1 Novolizer device.
Refill packs:
1 cartridge 200 metered doses filled with not less than 2.308 g of powder packed in a plastic container sealed by aluminium foil.
2 cartridges each 200 metered doses filled with not less than 2.308 g of powder packed in a plastic container sealed by aluminium foil.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

[To be completed nationally]

Manufacturer:

MEDA Pharma GmbH & Co. KG
Benzstr. 1
61352 Bad Homburg
Telefon: 06172-888-01
Telefax: 06172-888-2740
medinfo@medapharma.de

alternative:
MEDA Manufacturing GmbH
Neurather Ring 1
51063 Köln
Telefon: 0221-6472-0
Telefax: 0221-6472-696

alternative:

McDermott Laboratories T/A Mylan Dublin
Respiratory
Unit 25 Baldoyle Industrial Estate
Grange Road, Baldoyle
Dublin 13
Ireland

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

Austria:
Novolizer Salbutamol Meda 100 Mikrogramm Pulver zur Inhalation

Belgium und Luxembourg:
Novolizer Salbutamol 100 microgrammes, poudre pour inhalation

Ireland:
Novolizer Salbutamol 100 micrograms inhalation powder

Netherlands:
Salbutamol Novolizer 100 microgram, inhalatiepoeder

Portugal:
Salbutamol Novolizer 100 microgramas pó para inalação

France:
Ventilastin Novolizer 100 microgrammes/dose, poudre pour inhalation

Spain:
Ventilastin Novolizer 100 microgramos/dosis, polvo para inhalación

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INSTRUCTIONS FOR USE[1]

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.

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 the 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 dosage counter. Then a new cartridge has to be inserted. The cartridges may only be used in the original dry powder inhaler.

2. USAGE:

[1] Instructions for Use (*Gebrauchsanleitung*) in compliance with the *Medizinproduktegesetz* (German Law on Medical Devices)

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 200-60 is shown in steps of 20 and 60-0 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.

MEDA Pharma GmbH & Co. KG
Benzstr. 1
61352 Bad Homburg (Germany)

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