

Package leaflet: Information for the user

Budelin® Novolizer® 200 micrograms per actuation inhalation powder Budesonide

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 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 Budelin Novolizer 200 micrograms is and what it is used for
2. What you need to know before you use Budelin Novolizer 200 micrograms
3. How to use Budelin Novolizer 200 micrograms
4. Possible side effects
5. How to store Budelin Novolizer 200 micrograms
6. Contents of the pack and other information

1. What Budelin Novolizer 200 micrograms is and what it is used for

Budesonide, the active substance in Budelin Novolizer 200 micrograms, is a glucocorticoid (corticosteroid) for inhalation.

Budelin Novolizer 200 micrograms is used for regular treatment of persistent asthma.

NOTE:

Budelin Novolizer 200 micrograms should not be used for treatment of a sudden attack of respiratory distress (acute asthma attack or *Status asthmaticus* (asthma attacks occurring very frequently and/or persisting for several days)).

2. What you need to know before you use Budelin Novolizer 200 micrograms

Do not use Budelin Novolizer 200 micrograms if you are allergic to budesonide or to milk proteins, that are contained in small amounts in the excipient lactose monohydrate (see section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Budelin Novolizer 200 micrograms.
Contact your doctor if you experience blurred vision or other visual disturbances.

Take special care in using Budelin Novolizer 200 micrograms, if you are suffering from lung tuberculosis or fungal infection or from other infection of the airways. This also applies if you have been affected by these conditions in the past. Ask your doctor for advice.

Budesonide is not suitable for treatment of acute respiratory distress or severe continuous spasm of the bronchial tubes (*Status asthmaticus*). Your doctor will advise you to use a short-acting inhaled bronchodilating agent (bronchodilator) as rescue medication to relieve the acute symptoms of your complaints.

If you have a severe liver disease, the elimination of Budesonide may be impaired. This may lead to increased levels of Budesonide in your blood.

Any inhaled glucocorticoids may cause side effects, particularly when using high doses for prolonged periods. These effects are much less likely to occur with inhalation treatment than with the intake of glucocorticoid tablets. Possible effects include disorders in the function of the adrenal cortex, Cushing's syndrome, Cushingoid features (hormone disorder caused by high levels of cortisol in the blood with central obesity, 'moon face', thinning of the skin, hypertension, etc.), decrease in bone density, growth retardation in children and adolescents as well as eye disease (cataract and glaucoma), and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Therefore, it is important that the lowest dose is administered at which effective control of asthma is maintained.

Should periods of stress or emergencies (e.g. severe infections, injuries and surgery) occur within the first few months of switching from intake of tablets to inhalation treatment, it may be necessary to resume systemic administration of glucocorticoids in form of tablets or infusions. This applies also to patients who have received prolonged treatment with high doses of inhaled glucocorticoids. They may also have impaired adrenocortical function and may need systemic glucocorticoid cover during periods of stress and/or for elective surgery.

After switching to inhalation treatment, symptoms may occur that had been suppressed by the previous systemic treatment with glucocorticoids, e.g. symptoms of allergic rhinitis, allergic rash or rheumatic complaints. These symptoms should be treated in addition by suitable medication. Some patients might feel generally unwell in a non-specific way during the switching period despite maintenance or even improvement in respiratory function. In such a case, please, consult your doctor. He/she will then decide whether treatment can be continued as planned or if you have - for instance - symptoms of an insufficient function of the adrenal cortex conflicting with such continuation.

Other medicines and Budelin Novolizer 200 micrograms

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

Some medicines may increase the effects of Budelin Novolizer 200 micrograms and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: nelfinavir, ritonavir, cobicistat and medicine for the treatment of fungal disease: ketoconazole, itraconazole). Therefore, this combination should be avoided. If this is not possible the time interval between administration of these medicines and Budesonide should be as long as possible.

Raised plasma concentrations of corticosteroids and enhanced effects of corticosteroids have been observed in women also treated with oestrogens and contraceptive steroids, but no effect has been observed with budesonide and concomitant intake of low dose combination oral contraceptives. Because adrenal function may be suppressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values).

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.

Pregnancy

Most results from prospective epidemiological studies and world-wide post-marketing data have not been able to detect an increased risk for adverse effects for the foetus and newborn child from the use of inhaled budesonide during pregnancy. It is important for both foetus and mother to maintain an adequate asthma treatment during pregnancy. As with other drugs administered during pregnancy, the benefit of the administration of budesonide for the mother should be weighed against the risks to the foetus.

Breast-feeding

Budesonide is excreted in breast milk. However, at therapeutic doses no effects on the suckling child are anticipated. Maintenance treatment with inhaled budesonide (200 or 400 micrograms twice daily) in asthmatic nursing women results in negligible systemic exposure to budesonide in breast-fed infants. Therefore, Budelin Novolizer 200 micrograms can be used during breast feeding.

Driving and using machines

Budesonide has no influence on the ability to drive and use machines.

Budelin Novolizer 200 micrograms contains milk sugar (lactose), 10.7 mg of lactose monohydrate/delivered dose.

Normally, the content of lactose in a single dose does not cause any problems in people with lactose intolerance. If you are concerned that you may have an intolerance, you must talk to your doctor. Milk sugar (lactose) contains small amounts of milk protein.

3. How to use Budelin Novolizer 200 micrograms

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

Patients without previous treatment with glucocorticoids and patients previously treated with inhaled glucocorticoids

Unless otherwise prescribed by your doctor, the following dosage is recommended for:

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

Initial recommended dose:	1 -2 single doses (200 - 400 micrograms) once or twice daily
Maximum recommended dose:	4 single doses (800 micrograms) twice daily (daily dose: 1600 micrograms)

Children aged 6 to 12 years:

Initial recommended dose:	1 single dose (200 micrograms) twice or 200 - 400 micrograms once a day
Maximum recommended dose:	2 single doses (400 micrograms) twice daily (daily dose: 800 micrograms)

In case of once daily dosing, it is recommended to take this dose in the evening.

Children below 6 years of age:

Budelin Novolizer 200 micrograms is not recommended for use in children below age 6 due to insufficient data on safety and efficacy.

Please support your children in proper handling of the Novolizer device.

Children

It is recommended that the growth of children receiving prolonged treatment with inhaled glucocorticoids at large doses is regularly monitored.

Older people

Usually, no special dose adjustment is required. In general, the lowest effective dose required for a sufficient control should be used.

In case of deterioration of symptoms (recognized by e.g. persistent respiratory distress and increased use of other inhaled bronchodilating agents) you should seek advice from a medical doctor as soon as possible. If you have inhaled only once a day so far, it may become required in such a case to use the same dose twice daily now (in the morning and in the evening). In any case, you doctor should decide if your usual dose of Budelin Novolizer 200 micrograms needs to be increased.

Should you have the impression that the effect of Budelin Novolizer 200 micrograms is either too strong or too weak, discuss this with your doctor or pharmacist.

For the relief of acute symptoms of asthma, you should carry along a short acting inhaled bronchodilating agent (beta-2-agonist, such as Salbutamol) at all times.

When you switch from another Budesonide inhaler to Budelin Novolizer 200 micrograms, the treatment plan may have to be adjusted by your doctor.

Method of Administration

Inhalation use.

Inhale as shown in the Instructions for Use.

Important information for use

To reduce the risk of fungal infection in mouth and throat (oral candidiasis) and hoarseness it is recommended that inhalation be performed before meals and/or that the mouth is rinsed with water or the teeth are brushed after each inhalation.

Duration of treatment

Budelin Novolizer 200 micrograms is intended for long-term therapy. It should be used regularly according to the recommended treatment schedule even at times when no symptoms are experienced.

If you have not used glucocorticoids previously or have been treated occasionally only over a short period with glucocorticoids, regular use of Budelin Novolizer 200 micrograms as directed should lead to an improvement in breathing after approximately 10 days. However, extreme mucous congestion and inflammatory processes may obstruct the bronchial passages to such an extent that Budesonide cannot fully exert its effects in the lung. In such cases, initiation of therapy should be supplemented with administration of cortisone products (systemic glucocorticoids) in form of tablets. Later on, the tablet dose should be reduced gradually but inhalative therapy will be continued.

If you have used cortisone products for a prolonged period already, you should be switched to Budelin Novolizer 200 micrograms at a time when your symptoms are completely under control. Normally, function of the adrenal cortex is suppressed in this situation and therefore, intake of cortisone tablets (systemic corticoid administration) should be reduced gradually and must not be stopped abruptly. At the beginning of the switchover period, Budelin Novolizer 200 micrograms should be given in addition for approximately 10 days. Then, depending on your response, the daily dose of the cortisone tablets can be reduced gradually at intervals of one to two weeks.

If you inhale more Budelin Novolizer 200 micrograms than you should

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 Budelin Novolizer 200 micrograms

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

If you stop using Budelin Novolizer 200 micrograms

Do not stop treatment with the Budelin Novolizer 200 micrograms 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.

Most important side effects

Irritation of the oral mucosa (throat irritation) accompanied by difficulty in swallowing, hoarseness and cough may commonly occur.

Treatment with inhaled Budesonide may result in fungal disease in the mouth and the throat (oropharyngeal candidiasis). Experience has shown that this fungal infection occurs less often when inhalation is performed before meals and/or when the mouth is rinsed or the teeth are brushed after inhalation. In most cases this condition responds to topical anti-fungal therapy without discontinuing treatment with the Budelin 200 Novolizer.

As with other inhalation therapies, in rare cases bronchial spasm (paradoxical bronchospasm) may occur, manifested by a temporary exacerbation of the respiratory distress and a immediate increase in wheezing after dosing. Only in such a case, you should discontinue use of the Budelin 200 Novolizer without previous consultation and you must contact your doctor immediately.

Inhalation of larger doses over a prolonged period may lead to increased susceptibility to infection. The ability to adapt to stress can be impaired.

List of all other side effects

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

Depression, anxiety or feeling worried, cataract, muscle spasm, shaking (tremor), blurred vision

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

Allergic reactions (hypersensitivity) and swelling of the face, eyes, lips, mouth and throat (angioneurotic oedema), anaphylactic reaction; suppression of the function of the adrenal cortex (adrenal suppression), growth retardation in children and adolescents; restlessness, nervousness, abnormal behavior, over-excited or irritable (these effects are more likely to occur in children); skin reactions such as nettle rash (urticaria), eczema, topical inflammation of the skin (dermatitis), itching (pruritus), redness of the skin by excessively filled blood vessels (erythema) bruising, disturbance of voice and hoarse voice (in children).

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

Bone density is decreased

Frequency not known (frequency cannot be estimated from the available data):

Sleeping problems, aggression, excessive urge to be active accompanied by mental restlessness (psychomotor hyperactivity); glaucoma. Lactose-monohydrate contains small amounts of milk proteins and can therefore cause allergic reactions.

Occasionally, side effects may occur which are typical for systemic glucocorticosteroids. These side effects depend on the dosage, the period of treatment, concomitant or previous treatment with other glucocorticosteroids and the individual sensitivity.

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 this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Budelin Novolizer 200 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 in the original package. This medicinal product does not require any special temperature storage conditions.

In-Use storage conditions: Keep the Novolizer device tightly closed, in order to protect from moisture.

Information concerning in-use shelf-life

Exchange the cartridge six months after first opening.

Do not use the powder inhaler for more than 1 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 each and/or 20 cartridges containing 100 single doses each 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 further information

What Budelin Novolizer 200 micrograms contains

- The active substance is budesonide.
Each actuation (puff) contains 200 micrograms of budesonide.
- The other ingredient is Lactose monohydrate.

What Budelin Novolizer 200 micrograms looks like and contents of the pack

Budelin Novolizer 200 micrograms, inhalation powder, contains a white powder (1.09 g or 2.18 g) in a cartridge containing 100 or 200 metered doses packed in a container sealed by aluminium foil plus a Novolizer powder inhaler device..

All components are made of plastic materials.

Pack sizes:

Original sales packs:

- 1 cartridge containing 100/200 metered doses and 1 Novolizer powder inhaler device
- 2 cartridges containing 200 metered doses each and 1 Novolizer powder inhaler device

Refill packs:

- 1 cartridge containing 100 metered doses (UK and Ireland only)
- 1 cartridge containing 200 metered doses
- 2 cartridges containing 200 metered doses each

Not all pack sizes may be marketed.

Marketing Authorization Holder

Viatrix Products Limited,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer:

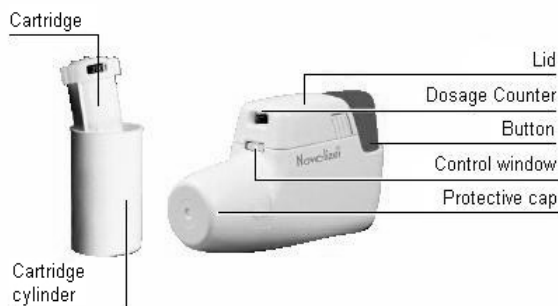
McDermott Laboratories T/A Mylan Dublin
Respiratory
Unit 25 Baldoyle Industrial Estate

Grange Road, Baldoyle
Dublin 13
Ireland

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INSTRUCTIONS FOR USE

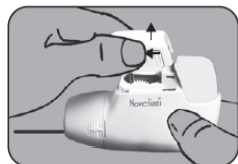
Novolizer®



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.

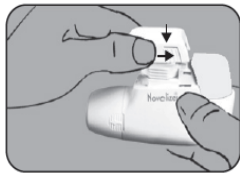


Refilling:

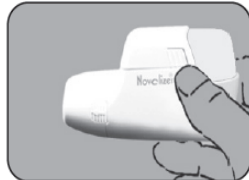
Note: The NOVOLIZER® Dry Powder Inhaler should be cleaned every time the cartridge is exchanged after removal of empty cartridge.

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 (→).



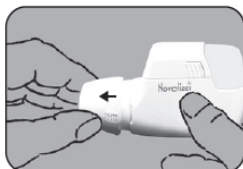
The NOVOLIZER® is now filled and ready for use.



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

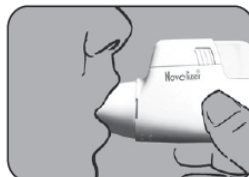
Whenever possible, sit or stand while inhaling. When using the NOVOLIZER® always keep it horizontal. First remove the protective cap (←).



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 (respectively 100)-60 is shown in steps of 20 and 60 (respectively 50)-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.

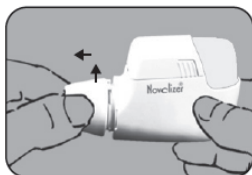
Inadvertent overdosing is not possible with the NOVOLIZER[®]. The click sound and the change of the colour in the control window indicate that inhalation has been performed correctly. If the colour of the control window does not change back to red, the inhalation should be repeated. If inhalation is 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.

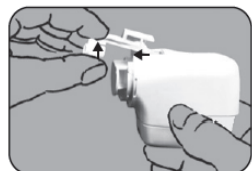
Remove protective cap and mouthpiece

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



Cleaning

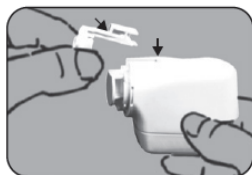
Now turn the NOVOLIZER[®] upside down. Grasp the loose dispensing slide and move it forwards (←) and upwards (↑). Any remaining powder can be removed by tapping lightly.



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

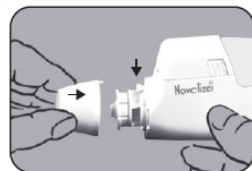
Assembly – Insert dosage slide

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.

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