

Package leaflet: Information for the user

Novolizer Budesonide® 400 micrograms 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

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1. What Novolizer Budesonide 400 micrograms is and what it is used for

Budesonide, the active substance in Novolizer Budesonide 400 micrograms, is a glucocorticoid (corticosteroid) for inhalation.

Novolizer Budesonide 400 micrograms is used for regular treatment of persistent asthma.

NOTE:

Novolizer Budesonide 400 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 Novolizer Budesonide 400 micrograms

Do not use Novolizer Budesonide 400 micrograms if you are allergic to budesonide or to milk proteins, that are contained in small amounts in the excipient lactose monohydrate.

Warnings and precautions

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

Take special care in using Novolizer Budesonide 400 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 Novolizer Budesonide 400 micrograms

Tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines, including medicines without a prescription.

Some medicines may increase the effects of Novolizer Budesonide 400 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, Novolizer Budesonide 400 micrograms can be used during breast feeding.

Driving and using machines

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

Novolizer Budesonide 400 micrograms contains milk sugar (lactose), 10.5 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 Novolizer Budesonide 400 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 single dose (400 micrograms) once or twice daily

Maximum recommended dose: 2 single doses (800 micrograms) twice daily (daily dose: 1600 micrograms)

Children aged 6 to 12 years:

Initial recommended dose: 1 single dose (400 micrograms) once a day

Maximum recommended dose: 1 single dose (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:

Novolizer Budesonide 400 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, your doctor should decide if your usual dose of Novolizer Budesonide 400 micrograms needs to be increased.

Should you have the impression that the effect of Novolizer Budesonide 400 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 Novolizer Budesonide 400 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

Novolizer Budesonide 400 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 Novolizer Budesonide 400 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 Novolizer Budesonide 400 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, Novolizer Budesonide 400 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 Novolizer Budesonide 400 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 Novolizer Budesonide 400 micrograms

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

If you stop using Novolizer Budesonide 400 micrograms

Do not stop treatment with the Novolizer Budesonide 400 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 Novolizer Budesonide 400 micrograms.

As with other inhalation therapies, in rare cases bronchial spasm (paradoxical bronchospasm) may occur, manifested by a temporary exacerbation of the respiratory distress and an immediate increase in wheezing after dosing. Only in such a case, you should discontinue use of the Novolizer Budesonide 400 micrograms 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.

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 Budesonide 400 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 20 cartridges containing 100 single doses each and/or 40 cartridges containing 50 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 Novolizer Budesonide 400 micrograms contains

- The active substance is budesonide. Each actuation (puff) contains 400 micrograms of budesonide.
- The other ingredient is Lactose monohydrate.

What Novolizer Budesonide 400 micrograms looks like and contents of the pack

Novolizer Budesonide 400 micrograms, inhalation powder, contains a white powder (0.545 g or 1.09 g) in a cartridge containing 50 or 100 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 50/100 metered doses and 1 Novolizer powder inhaler device

2 cartridges containing 100 metered doses each and 1 Novolizer powder inhaler device

Refill packs:

1 cartridge containing 50/100 metered doses

2 cartridges containing 100 metered doses 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:

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

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

Austria

Novolizer® Budesonid Meda 400 Mikrogramm Pulver zur Inhalation

Belgium and Luxembourg:

Novolizer® Budesonide 400 microgrammes, poudre pour inhalation

France:

Novopulmon® Novolizer® 400 microgrammes/ dose, poudre pour inhalation

Germany:

Novopulmon® 400 Novolizer® , Pulver zur Inhalation

Ireland:

Novolizer® Budesonide 400 micrograms inhalation powder

United Kingdom (Northern Ireland):

Budelin® Novolizer® 400 micrograms per actuation inhalation powder

Italy:

Budesonide Viatris® Novolizer® 400 microgrammi polvere per inalazione

The Netherlands:

Budesonid Novolizer® 400 microgram, inhalatiepoeder

Portugal:

Budesonido Novolizer® 400 microgramas pó para inalação

Spain:

Novopulm® Novolizer® 400 microgramos, polvo para inhalación

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