

Budecort Inhaler

1. Brand Name

Budecort

2. Generic name

Budesonide

3. Dosage Form

Metered dose Inhaler: 200mcg/dose

4. Indication & Usage

Budesonide is an anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity.

Budecort Inhaler is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients. It is also indicated for patients requiring oral corticosteroid therapy for asthma. Many of those patients may be able to reduce or eliminate their requirement for oral corticosteroids over time.

Budecort Inhaler is not indicated for the relief of acute bronchospasm.

5. Dosage & Administration

Adults (including elderly) and children over 12 years:

200-1600 mcg daily, in divided doses.

200 micrograms twice daily, in the morning and in the evening. During periods of severe asthma the daily dosage can be increased up to 1600 micrograms.

In patients whose asthma is well controlled, the daily dose may be reduced below 400 micrograms but should not go below 200 micrograms.

Patients should be maintained on the lowest dose that will effectively control symptoms.

Children (2-12 years):

200-800 mcg daily, in divided doses.

The dose should be reduced to the minimum needed to maintain good asthma control.

6. Adverse reactions

Clinical trials and reports suggest that the following adverse drug reactions may occur:

Mild irritation in the throat, Candida infection in the oropharynx, hoarseness, coughing, nasopharyngitis, nasal congestion, pharyngitis, allergic rhinitis, viral upper respiratory tract infection, nausea, viral gastroenteritis, otitis media, oral candidiasis, respiratory infection, sinusitis, headache, pain, back pain, fever, neck pain, syncope, abdominal pain, dry mouth, vomiting, weight gain, fracture, myalgia, hypertension, migraine, ecchymosis, insomnia, infection, taste perversion, voice alteration, asthenia, dyspepsia, arthralgia, increased cough, rhinitis were more common than placebo in the clinical trials with budesonide. The Candida infection in the oropharynx is due to drug deposition. Hence, patients should be advised to rinse out their mouth

with water after each dosing to minimize the risk. The incidence should be less with the spacer, as these reduce oral deposition.

Nervousness, restlessness, depression, behavioral disturbances, immediate and delayed hypersensitivity reactions, including rash, contact dermatitis, urticaria, angioedema and bronchospasm and anaphylactic reaction, skin bruising, dysphonia and hoarseness in children are some rare undesirable events reported. As with other inhalation therapy, paradoxical bronchospasm may occur in very rare cases.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, and glaucoma. The effect is probably dependent on dose, exposure time, concomitant and previous steroid exposure, and individual sensitivity.

The susceptibility to infection can be increased. The ability to adapt to stress can be impaired. There is an increased risk of pneumonia in patients with newly diagnosed COPD starting treatment with inhaled corticosteroids.

The following adverse reactions have been reported during post-approval use of budesonide. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune system disorders: immediate and delayed hypersensitivity reactions including anaphylactic reaction, angioedema, bronchospasm, rash, contact dermatitis, urticaria, and cough, wheezing or bronchospasm.

Endocrine disorders: symptoms of hypocorticism and hypercorticism.

Eye disorders: cataracts, glaucoma, increased intraocular pressure.

Psychiatric disorders: psychiatric symptoms including psychosis, depression, aggressive reactions, irritability, nervousness, restlessness, and anxiety.

Respiratory, thoracic, and mediastinal disorders: throat irritation

Skin and subcutaneous tissue disorders: skin bruising, erythema, pruritus.

Musculoskeletal, connective tissue and bone disorders: Bone density decreased

7. Contraindications

History of hypersensitivity to budesonide or any of the excipients.

Budecort Inhaler is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

8. Drug interactions

The metabolism of budesonide is primarily mediated by CYP3M, one of the cytochrome p450 enzymes. Inhibitors of this enzyme, e.g. Ketoconazole and Itraconazole, can therefore increase systemic exposure to budesonide. Other potent Inhibitors of CYP3A4 (e.g. ritonavir, clarithromycin) are also likely to markedly increase plasma levels of budesonide.

9. Warnings & Precautions

Special care is needed in patients with pulmonary tuberculosis and viral infections of the airways.

Non-steroid-dependent patients: A therapeutic effect is usually reached within 10 days. In patients with excessive mucus secretion in the bronchi, a short (about 2 weeks) additional oral corticosteroid regimen can be given initially. After the course of the oral drug, Budesonide Respules alone should be sufficient therapy.

Steroid-dependent patients: When transfer from oral corticosteroid to treatment with budesonide is initiated, the patient should be in a relatively stable phase. Budesonide is then given, in combination with the previously used oral steroid dose, for about 10 days.

After that, the oral steroid dose should be gradually reduced (by, for example, 2.5 mg prednisolone or the equivalent each month), to the lowest possible level. In many cases, it is possible to completely substitute budesonide for the oral corticosteroid.

During transfer from oral therapy to budesonide, a generally lower systemic corticosteroid action will be experienced, which may result in the appearance of allergic or arthritic symptoms such as rhinitis, eczema and muscle and joint pain. Specific treatment should be initiated for these conditions. A general insufficient glucocorticosteroid effect should be suspected if, in rare cases, symptoms such as tiredness, headache, nausea and vomiting should occur. In these cases a temporary increase in the dose of oral Glucocorticosteroids is sometimes necessary.

As with other inhalation therapy, paradoxical bronchospasm may occur, with an immediate increase in wheezing after dosing. If a severe reaction occurs, treatment should be reassessed and an alternative therapy instituted if necessary.

Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than the recommended doses, may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during period of stress or elective surgery.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These affects are much less likely to occur than with oral corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma.

It is important, therefore, that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed, with the aim of reducing the dose of inhaled corticosteroid, if possible, to the lowest dose at which effective control of asthma is maintained. In addition, consideration should be given to referring the patient to a pediatric respiratory specialist.

Budesonide inhaler is not intended for rapid relief of acute episodes of asthma where an inhaled short-acting bronchodilator is required. If patients find short-acting bronchodilator treatment ineffective, or they need more inhalations than usual, medical attention must be sought. In this situation consideration should be given to the need for or an increase in their regular therapy, e.g., higher doses of inhaled budesonide or the addition of a long-acting beta agonist, or for a course of oral glucocorticosteroid.

Concomitant treatment with ketoconazole and Itraconazole or other potent CYP3A4 inhibitors should be avoided. If this is not possible, the time interval between administrations of the interacting drugs should be as long as possible. A reduction in the dose of budesonide should also be considered.

Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract, untreated systemic fungal, bacterial, viral or parasitic infections, or ocular herpes simplex.

If clinical symptoms become exacerbated by acute respiratory tract infections, treatment with appropriate antibiotics should be considered. The dose of budesonide can be adjusted as required and, in certain situations systemic treatment with Glucocorticosteroids may be indicated.

If no improvement of symptoms or adequate asthma control is seen within 14 days of treatment, medical advice is sought for either adjusting the dose or clarifying correct inhalation procedure.

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids. The clinical significance of small changes in BMD with regard to long-term consequences such as fracture is unknown. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, post-menopausal status, tobacco use, advance age, poor nutrition, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care.

Glaucoma, increased intraocular pressure, and cataracts have been reported following the long-term administration of inhaled corticosteroids, including budesonide. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

10. Pregnancy & Lactation

Pregnancy Category B

Results from a large prospective epidemiological study and from worldwide post marketing experience indicate no increased teratogenic risk associated with the use of inhaled budesonide. The administration of budesonide during pregnancy requires that the benefits for the mother be weighed against the risk for the fetus. Inhaled Glucocorticosteroids should be considered in preference to oral Glucocorticosteroids because of the lower systemic effects at the doses required to achieve similar pulmonary responses.

Hypoadrenalinism may occur in infants born of mothers receiving corticosteroids during pregnancy. Such infants should be carefully observed.

Lactation

Budesonide is excreted in breast milk. Budecort Inhaler should be used in nursing women only if clinically appropriate. Prescribers should weigh the known benefits of breastfeeding for the mother and the infant against the potential risks of minimal budesonide exposure in the infant. Dosing considerations include prescription or titration to the lowest clinically effective dose and use of Budecort Inhaler immediately after breastfeeding to maximize the time interval between dosing and breastfeeding to minimize infant exposure. However, in general, Budecort Inhaler use should not delay or interfere with infant feeding.

11. Storage condition

Store below 30°C.

Protect from frost.

Pressurized canister, keep away from sunlight and heat. Do not puncture, break or burn even when apparently empty.

Shake well before each use.
Keep away from eyes.
Keep out of reach of children.

12. Packaging

Each pack contains 1 inhaler, 200 metered doses each, with dose indicator.

13. License Holder

CIPLA LTD/ India

14. Marketing Authorization Holder in IRAN

Koushan Pharmed