For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Budecort 0.5 mg Respules
Budecort 1 mg Respules

INN: Budesonide

DOSAGE FORM: Inhalation suspension

COMPOSITION:

Budecort 0.5 mg Respules
Each 2 ml respule contains
Budesonide BP ..... 0.5 mg

Budecort 1 mg Respules
Each 2 ml respule contains
Budesonide BP ..... 1 mg

THERAPEUTIC CLASS: Anti asthmatic

DESCRIPTION:

Budecort 0.5 mg Respules
A white homogenous redispersible suspension filled in FFS vials

Budecort 1 mg Respules
A white homogenous redispersible suspension filled in FFS vials

Pharmacological properties

Budesonide is a potent glucocorticoid that binds with high affinity to the glucocorticoid receptor. It also has a high local anti-inflammatory effect. Budesonide reduces the number of inflammatory cells, such as eosinophils, lymphocytes and mast cells, and restores airway epithelial integrity in bronchial biopsy specimens obtained from mild asthmatic patients. Inhaled budesonide also reduces indices of eosinophil activation in asthma. Budesonide inhibits plasma exudation through the endothelial barrier of the bronchial vasculature and therefore, their administration leads to a reduction in airway edema. Budesonide also inhibits phospholipase A_2 activity, and by this means reduces the formation of prostaglandins and leukotrienes in the airway.

Budesonide undergoes an extensive biotransformation in the liver to metabolites of low glucocorticoid activity. The glucocorticosteroid activity of the major metabolites, 6β-hydroxybudesonide and 16 ∝-hydroxyprednisolone is less than 1% of that of budesonide. Of the fraction of budesonide which is swallowed approximately 90% is inactivated at first passage through the liver. The maximal peak plasma concentration after inhalation is about 3.5 nmol/L and is reached after about 20 minutes. Plasma half-life is approximately 2h and plasma clearance is 0.9-1.4 L/min. Plasma protein binding is 86-90%, mainly to albumin and not to transcortin. Budesonide is extensively distributed. Metabolic transformation of budesonide in liver is not affected by drugs which inhibit some forms of cytochrome P450 (eg.cimetidine).

Indications

Budecort Respules are indicated in the treatment of bronchial asthma when replacement or reduction in oral steroid therapy is desirable. **Budecort** Respules are also recommended when other modes of steroid therapy are unsuitable. It is also indicated in the treatment of croup.

Contraindications

Hypersensitivity to budesonide or other ingredients.

Side Effects

Budesonide is generally well tolerated. Mild irritation in the throat, coughing, hoarseness and Candida infection in the oropharynx have been reported. Skin reactions, urticaria, rash, dermatitis etc. may, in rare cases, occur in association with local corticosteroid therapy. Facial skin irritation has occurred in some cases when a nebuliser with face mask has been used. To prevent irritation the facial skin should be washed after use of the face mask. Psychiatric symptoms such as nervousness, restlessness and depression as well as behavioural disturbances in children have been observed. In rare cases, through unspecified mechanism, drugs for inhalation may cause bronchospasm. The incidence of oropharyngeal candidiasis can be kept to a minimum by asking patients to rinse their mouth after each inhalation.

Warnings & Precautions

Budecort Respules are not indicated for rapid relief of bronchospasm.

Budecort Respules are not suitable as sole therapy for the treatment of status asthmaticus or other acute exacerbations where intensive measures are required. Particular care is needed in patients who are being transferred from oral corticosteroid to **Budecort** respules. Special care is needed in patients with lung tuberculosis and fungal and viral infections. Children who are on

immunosuppressant drugs are more susceptible to infections than healthy children. Chickenpox and measles, for example, can have a more serious or even fatal course in children on immusuppressant corticosteroids. During long term therapy, monitoring of hematological and adrenal function is advisable.

Recommended Dosage, Dosage schedule and Route of administration

The dosage of **Budecort** Respules is individualized.

The initial dose or during periods of severe asthma or while reducing oral corticosteroids:

Adults : 1-2 mg twice daily.

Children : 0.5-1 mg twice daily.

Maintenance dose

The maintenance dose should be individualized. After the desired clinical effect has been obtained, the maintenance dose should be gradually reduced to the smallest amount necessary for control of symptoms.

Adults : 0.5-1 mg twice daily.

Children : 0.25-0.5 mg twice daily.

Croup : 2 mg as a single dose or two doses of 1 mg 30 minutes apart.

Patients dependent on oral steroids

When transferring a patient from oral steroids to **Budecort** Respules the patient should be in a relatively stable phase. A high dose of **Budecort** Respules is given in combination with the previously used steroid for about 10 days. After that, the oral dose is gradually reduced (for example 1 mg prednisolone or the equivalent, every 4 days) to the lowest possible level. The dose of **Budecort** Respules should not be altered while the patients remains on oral corticosteroids. In many cases, it is possible to completely substitute the oral steroid with **Budecort** Respules. In other patients a low oral steroid maintenance dose may be necessary.

During transfer from oral therapy to **Budecort** Respules a lower systemic steroid action may be experienced. Earlier allergic symptoms may recur or patients may suffer from tiredness, headache, muscle and joint pain or occasionally nausea and vomiting.

Patients not dependent on oral steroids

Treatment with the recommended doses of **Budecort** Respules usually gives a therapeutic effect within 10 days. In patients with excessive mucus secretion in the bronchi an initial short course (about 2 weeks) of an oral corticosteroid commencing with a high dose and gradually reducing, should be given in addition to **Budecort** respules.

Treatment should be continued for atleast one month before determining the maximal response to a given dose of **Budecort** Respules.

Data from various *in vivo* studies have estimated that the dose of nebulised budesonide delivered to the patient ranges between 11-22% of the normal dose depending on the nebulising equipment used. The use of a tight sealing facemask in infants and young children, seems to maximize the delivered dose of budesonide . The nebulisation time and the dose delivered is dependent on flow rate, volume of nebuliser chamber and volume fill. A suitable fill for most nebulisers is 2-4 ml.

Some sedimentation may occur during storage of **Budecort** Respules. If this does not readily resuspend on shaking the respule should be discarded.

Symptoms and treatment for overdosage and antidote(s) :

Acute overdosage with Budecort Respules should not be a clinical problem. Habitutal overdosing may cause hypercorticism and adrenal suppression. Withdrawal of Budecort respules or a decrease in dose will abolish these effects, although the normalization of the HPA axis may be a slow process.

Packing/ Pack Size

Packing : Each carton containing 4 combipacks having 5 respules of 2 ml each.

Pack Size : Respule of 2 ml.

Storage conditions, user instructions and pharmaceutical precautions

Storage condition: Store below 30°C. Protect from light. Do not freeze.

Presentation

Budecort 0.5 mg Respules	Respule of 2 ml
Budecort 1 mg Respules	Respule of 2 ml

Cipla

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