

Budison Nebuliser Suspension

Budesonide BP 0.5 mg / 2 ml

COMPOSITION

Budison Nebuliser Suspension: Each 2 ml ampoule contains Budesonide BP 0.5 mg.

PHARMACOLOGY

Budison Nebuliser Suspension is consisting of Budesonide is a corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity. Budesonide has approximately a 200-fold higher affinity for the glucocorticoid receptor and a 1000-fold higher topical anti-inflammatory potency than cortisol.

INDICATIONS

Budison Nebuliser Suspension is indicated for the maintenance treatment and as prophylactic therapy of asthma.

DOSAGE & ADMINISTRATION

Children (3 months to 12 years): 0.25 to 0.5 mg twice daily. In some cases, the dosage may be further increased up to 1 mg twice daily.

Adults: usually 1 to 2 mg twice daily.

CONTRAINDICATION

Hypersensitive to any of the ingredients of Budison Nebuliser Suspension.

WARNING & PRECAUTIONS

Adrenal insufficiency can occur in asthmatic patients who are transferred from systemically active corticosteroids to inhaled corticosteroids. Particular care is needed in patients who required high-dose emergency corticosteroid therapy. Patients previously on high doses of systemic steroids may regain earlier symptoms not related to asthma such as rhinitis and eczema when transferred from oral therapy to Budison Nebuliser Suspension. The development of pharyngeal and laryngeal candidiasis is cause for concern because the extent of its penetration into the respiratory tract is unknown. For patients with TB, fungal or viral infections special care is needed. Avoid abrupt withdrawal when switching from systemic therapy to oral or orally inhaled corticosteroid.

SIDE EFFECTS

Most commonly reported adverse events are rhinitis, coughing, otitis media, moniliasis, vomiting, diarrhea, abdominal pain, ear infection, epistaxis, conjunctivitis & rash.

USE IN SPECIAL GROUPS

Use in pregnancy: There are no adequate and well-controlled studies in pregnant women. Budesonide should be used during pregnancy only if the potential benefits outweigh the risk to the fetus.

Use in lactation: It is not known whether Budesonide is excreted in human milk. Because other corticosteroids are excreted in human milk, caution should be exercised if Budesonide is administered to nursing women.

DRUG INTERACTIONS

Budesonide has not been observed to interact with any drug used for the treatment of asthma. Slight inhibitory effect on hepatic metabolism of Budesonide, caused by cimetidine. CYP3A4 inhibitors like ritonavir and azole antifungals (e.g. ketoconazole and itraconazole) increase the systemic exposure to Budesonide. Therefore, concomitant use of Budesonide and ritonavir or azole antifungals should be avoided.

STORAGE

Store below 25°C, keep in dry place & protect from light. Keep out of the reach of children.

PACKING

Budison Nebuliser Suspension: Each box contains 5 ampoules in alu-pvc blister pack.

Manufactured by:
 **ARISTOPHARMA LTD.**
Shampur-Kadamtail I/A, Dhaka-Bangladesh

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