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

Betamethasone (As Sodium Phosphate) & Betamethasone (As Dipropionate) Injection

AMERICAN BETASTAL-BD Injection

For IM Use

Composition: Each ampoule 2ml contains:

Betamethasone (As Sodium Phosphate)	USP	4mg
Betamethasone (As Dipropionate)	USP	10 mg
Water for Injection	USP	q.s.

Pharmacological Properties:

BETASTAL-BD sterile aqueous injectable suspension provides a combination of highly soluble and Vasoconstriction, slightly soluble esters of Betamethasone that produce anti-inflammatory, anti rheumatic, and anti-allergic effects. Prompt therapeutic activity is achieved by the soluble ester Betamethasone sodium phosphate, which is quickly absorbed after injection. Sustained activity is provided by Betamethasonc dipropionate which is only slightly soluble and becomes a repository for slow absorption, thereby controlling symptoms over a prolonged period. The small crystal size of Betamethasone dipropionate permits the use of a fine -gauge needle for intradermal and intralesional administration. The effect of betamethasone on sodium and water retention are markedly less than those of other corticosteroids.

Indications:

BETASTAL-BD aqueous suspension is indicated for the treatment of acute and chronic corticosteroid-responsive disorders such as the following conditions

• Musculoskeletal and soft tissue conditions Rheumatoid arthritis, osteoarthritis, bursitis, ankylosing spondilitis, radiculitis, sciatica and disc, Musculoskeletal polytendinitis.

•Allergic and dermatological Conditions Bronchial asthma, eczema, hay fever, bronchitis and perennial allergic rhinitis, insect bites, hypertrophic lichen plans, alopecia areata, discoid lupus erythematosus, psoriasis, keloids. pemphigus, dermatitis herpetiformis, and periarteritis nodosa. Immunosuppressive diseases: Ulcerative colitis, neoplasia, Crohn's disease, glomerulitis and nephritis.

Contraindications:

The preparation is contra indicated in the following conditions:

• Hypersensitivity to the components. - Systemic fungal infections.

Precautions:

The use of **BETASTAL-BD** is not recommended unless in case or extreme necessity in patients with the following conditions:

- Peptic ulcers-osteoporosis-patients with psychological disorders **BETASTAL-BD** should be used with caution in the following conditions:

*patients with congestive heart failure - Hypertension - Epilepsy - Glaucoma -Uraemia -Viral infections -Tuberculosis

Drug Interactions:

*Concurrent administration of Phenytoin, Phenobarbital , or ephedrine may reduce the therapeutic effects of **BETASTAL-BD**.

• Excessive corticosteroid effects may occur in patients receiving both a corticosteroid and an estrogen.

• Concurrent use of corticosteroid with diuretics may lead to disturbances of electrolyte balance.

• Concurrent use of corticosteroid with cardiac glycosides may enhance the possibility of arrhythmias or digitalis toxicity.

• Concomitant use of corticosteroid with coumarin-type anticoagulants may increase or decrease the anticoagulants effects.

Side Effects:

Adverse effects occur in general, fairly equally with all corticosteroid preparations Disturbances of electrolyte balance are common with Betamethasone, which has a little or no mineralocorticoid activity. Other excessive metabolic effects lead to mobilization of calcium and phosphate, with osteoporosis and spontaneous fractures and efficacy disturbance in the insulin requirements of diabetic patients, or, the occurrence of increased susceptibility to all kinds of infections including fungal infections such as Candida infections in particular in patients treated with corticosteroid, especially when these compounds are administered frequently and for a long-term treatment. Metabolic disorders, psychological, dermatological, and digestive disorders may occur.

Packing: 10 x 2ml Ampoule in a unit carton along with package insert & 10 unit carton in an outer box.

Storage: Store in a cool, dry & dark place, at a temperature not exceeding 25°C. Protected from light. Do not freeze.

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