# BEPROGENT CREAM

HOE
Est. 1979

**NAME AND STRENGTH OF ACTIVE SUBSTANCES:** Betamethasone dipropionate 0.064% w/w (equiv. to Betamethasone 0.05% w/w) and Gentamicin sulphate 0.17% w/w (equiv. to Gentamicin 0.1% w/w).

**PRODUCT DESCRIPTION :** A white cream.

Other ingredients: White Soft Paraffin, Liquid Paraffin, Methylparaben, Propylparaben, Propylene Glycol, Macrogol Cetostearyl Ether, Cetostearyl Alcohol, Sodium Dihydrogen Phosphate, Phosphoric acid 85% and Purified water.

**PHARMACODYNAMICS :** *Betamethasone dipropionate* is a topically active fluorinated corticosteroid which has anti-inflammatory, antipruritic and vasoconstrictive actions. *Gentamicin sulphate* is a broad spectrum aminoglycoside antibiotic which is bactericidal. It is effective against many strains of gram-negative bacteria and *Staphylococcus aureus.*

**PHARMACOKINETICS :** *Corticosteroids* are extensively bound to plasma protein. Only unbound corticosteroids has pharmacological effects or is metabolised.

They are metabolised mainly in the liver and also in the kidney, and are excreted in the urine. *Gentamicin sulphate* is a bactericidal antibiotic which is active against a wide variety of pathogenic gram-positive and gram-negative bacteria. When applied topically to large areas of denuded body surface as the case of burn patients, plasma concentrations can reach 1mcg/ml, and 2% of the drug used may appear in the urine.

**INDICATIONS :** Treatment of impetigo, erythyma and other localised primary bacterial skin infection with a Gram-negative component and also for secondary bacterial infections complicating other pre-existing dermatoses.

**CONTRAINDICATION :** Hypersensitivity to betamethasone dipropionate, gentamicin sulphate or any component in the base.

**DRUG INTERACTION :** Not known.

**ADVERSE EFFECT :** *Betamethasone Dipropionate* - Reported local adverse reactions are burning sensation, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids. *Gentamicin Sulphate* - Ototoxicity and nephrotoxicity has been reported often in the topical treatment of severe burns with gentamicin. Hypersensitivity reactions have been reported after local use.

**WARNINGS AND PRECAUTIONS :** Discontinue use if irritation, sensitivity or other reaction develop and institute appropriate treatment. Corticosteroid applied to the skin can be absorbed in sufficient amount to produce systemic effects such as hypothalamic-pituitary-adrenal axis suppression, manifestation of Cushing's syndrome, hyperglycaemia and glucosuria. Thus suitable precautions should be taken during prolonged treatment, when treating extensive body surface areas, when using the occlusive technique and when treating children (because of a larger skin surface area to bodyweight ratio). Visual disturbance may be reported with systemic and topical corticosteroids use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma, or rare diseases such as central serous chorioretinopathy (CSCR) which may have been reported after use of systemic and topical corticosteroids. Prolong use of a preparation containing an antibiotic may result in overgrowth of non susceptible organisms including fungi. If this occurs, discontinue use and institute appropriate therapy. Not suitable for ophthalmic use.

Use of topical gentamicin preparation in closed hospital settings is actively discouraged.

**PREGNANCY AND LACTATION :** Safety of it's use during pregnancy and lactation has not been established. Thus it should be used only if the potential benefit outweighs the potential risk to the foetus or nursing infant.

**RECOMMENDED DOSAGE :** Apply to the affected area twice daily.

**ROUTE OF ADMINISTRATION :** Topical.

**OVERDOSAGE :** If hypothalamic-pituitary-adrenal axis suppression is found, then the drug should be withdrawn, frequency of application reduced or a weaker steroid used. Supplementary systemic corticosteroids may be required if signs and symptoms of steroid withdrawal occur.

**PACKING :** Plastic jar of 450g (for export only) and aluminium tubes of 15g. Not all pack size may be available locally.

**STORAGE :** Keep container well closed. Protect from light. Store below 30°C.

For external use only. Keep out of reach of children.

Recommended shelf-life: 3 years.

**MANUFACTURED BY :**

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