ORGANON **ARTWORK**

PRODUCT NAME: DIPGENTA + CREAM

PRODUCT CODE: 8087430-805

COMPONENT: Leaflet

DIMENTIONS: L: 130 mm x H: 120 mm

SITE: TORRENT PHARMA

DRAWING NO.: NA

OLD REF. CODE : 8059022-805

PANTONE
Rubine Red C

Ver 1 - 11-07-2022 - New Artwork Creation.
Ver 2 - 18-08-2022 - PHARMACODE REMOVE
Ver 3 - 17-10-2022 - CORRECTION DONE
Ver 4 - 25-11-2022 - CORRECTION DONE
Ver 5 - 20-01-2023 - CORRECTION DONE

ICON GRAPHICS

Pharmacode
Minicode **: 218**

FRONT SIDE
SAME SIZE ARTWORK
Flat size: L: 130 mm x H: 120 mm
Folded size: 130 mm x 21 mm (L x W)

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

DIPGENTA® + CREAM

Brand of Clobetasol Propionate IP (0.05% w/w) and Neomycin Sulphate IP equivalent to neomycin (0.5% w/w)

FOR DERMATOLOGIC USE ONLY

NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE

DESCRIPTION: DIPGENTA®+Cream contains the active compound Clobetasol propionate, a synthetic corticosteroid and neomycin sulphate, an aminoglycoside antibiotic, for topical dermatologic use only.

Clobetasol is an analog of prednisolone having a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity. Chemically, clobetasol propionate is (11ß, 16ß)-21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-pregna-1, 4-diene-3, 20-dione, with empirical formula $C_{25}H_{32}ClFO_5$.

Neomycin sulphate is the sulphate salt of neomycin B and C, produced by the growth of Streptomyces fradiae.

COMPOSITION:

Clobetasol Propionate IP	0.05% w/w
Neomycin Sulphate IP eq to Neomycin base	0.5% w/w
Chlorocresol IP (as preservative)	0.10% w/w
in a cream base	

ACTIONS: The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common prescursor, arachidonic acid. Corticosteroids are also thought to act by the induction of phospholipase A2 inhibitory proteins.

Neomycin acts on the bacteria by interfering with bacterial protein synthesis by binding to 30 S ribosomes. The antibacterial spectrum of Neomycin includes specific organisms which are susceptible to it and generally includes all medically important aerobic gram negative bacilli except Pseudomonas aeruginosa. Anaerobic bacteria are resistant. Staphylococcus aureus and Staph. epidermidis are highly sensitive, but all streptococci are relatively resistant.

PHARMACOKINETICS: Topical corticosteroids can be absorbed from normal intact skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

INDICATIONS AND USAGE: DIPGENTA®+Cream is super high potency corticosteroid and antibiotic formulation indicated for the treatment of corticosteroid-responsive dermatoses with secondary infection caused by organisms susceptable to neomycin.

Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g/ week because of the potential for the drug to supress the hypothalamic-pituitary-adrenal (HPA) axis.

Use in pediatric patients under 12 years of age is not recommended.

As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary.

DOSAGE AND ADMINISTRATION: Apply a thin layer of DIPGENTA®+Cream to the affected skin areas twice daily and rub in gently and completely.

For some patients, adequate maintenance therapy may be achieved with less frequent application.

DIPGENTA®+ Cream should not be used with occlusive dressings.

CONTRAINDICATIONS: DIPGENTA®+Cream is contraindicated in those patients with a history of sensitivity reactions to any of its components. Not for use in the eyes or in the external ear canal if the eardrum is perforated. It is contraindicated in fungal, viral and tuberculous lesions of the skin.

ADVERSE REACTIONS: The most frequent adverse reactions reported for clobetasol propionate cream were burning, irritation, itching and stinging sensation. Less frequent adverse reactions were itching, skin atrophy, cracking and fissuring of the skin, stinging, cracking, erythema, folliculitis, numbness of fingers, skin atrophy, and telangiectasia.

Cushing syndrome has been reported in infants and adults as a result of prolonged use of topical clobetasol propionate formulations. The following additional local adverse reactions have been reported with topical corticosteroids - dryness, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, irritation, striae, and miliaria.

Neomycin occasionally causes skin sensitization. Ototoxicity and nephrotoxicity have been reported. The reaction most frequently occuring is allergic sensitization.

PRECAUTIONS: DIPGENTA®+Cream should not be used on the face, groin, or axillae. DIPGENTA®+Cream is not for ophthalmic use. Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from treatment.

120 mm

130 mm

BACK SIDE
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Manifestations of Cushing syndrome, hyperglycemia, and glucosuri can also be produced in some patients by systemic absorption of topical corticosteroids while on therapy.

Patients applying a topical steroid to a large surface area or to areas a under occlusion should be evaluated perodically for evidence of HPA axis suppression.

Patients receiving super-potent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA suppression.

Clobetasol Cream produced HPA axis suppression when used at doses as low as 2 g/day for 1 week in patients with eczema.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation or sensitization develops with the use of DIPGENTA®+Cream, treatment should be discontinued and appropriate therapy instituted.

As with any antibacterial preparation, prolonged use may result in overgrowth of the non-susceptible organisms including fungi.

Due to the concern of nephrotoxicity and Ototoxicity associated with neomycin, this combination should not be used over wide surface area.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY : Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate and neomycin. Studies in the rat following subcutaneous administration at dosage levels up to 50 mcg/kg/day revealed that the females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.

Clobetasol propionate was nonmutagenic in 3 different test systems: the Ames test, the Sacchromyces cerevisiae gene conversion assay, and the E. coli B WP2 fluctuation test.

USE DURING PREGNANCY AND NURSING MOTHERS: Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PEDIATRIC USE: Safety and effectiveness of DIPGENTA®+Cream in pediatric patients have not been established. Use in pediatric patients under 12 years of age is not recommended. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids.

GERIATRIC USE: While the number of patients treated with topical clobetasol propionate is too small to permit separate analysis of efficacy and safety, the adverse reactions reported are similar to those reported by younger patients.

OVERDOSAGE: *Symptoms* : Excessive or prolonged use of topical corticosteroids can suppress pituitary-adernal function, resulting in secondary adernal insuffciency and produce manifestations of hypercorticism, including Cushing's disease.

Treatment : Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised,

Information for Patients: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is for external use only.
2. It is to be used as directed by the physician.
3. This medication should not be used for any disorder other than that for which it was prescribed.
4. Avoid contact with the eyes
5. The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive unless directed by the physician.

STORAGE: Store below 30°C protected from light. Do not freeze.

Keep out of sight and reach of children

HOW SUPPLIED: DIPGENTA®+Cream in a cream base as 20g tube.

Manufactured by: Torrent Pharmaceuticals Ltd.
Plot No. 810, Sector III, Industrial Area,
Pithampur, Dist. Dhar - 454 775 (M.P.), India.

Marketed by: **FULFORD (INDIA) LIMITED**
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