Drugfield PHARMACEUTICALS LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Drugent®-HC Cream

(Gentamicin Sulphate 0.35% $^{W}/_{W}$ + Hydrocortisone Acetate 1% $^{W}/_{W}$)

1. NAME OF THE MEDICINALPRODUCT

Drugent®-HC Cream (Gentamicin Sulphate 0.35%$^{W}/_{W}$ + Hydrocortisone Acetate 1%$^{W}/_{W}$

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each ml contains Gentamicin Sulphate 0.35%$^{W}/_{W}$ + Hydrocortisone Acetate 1%$^{W}/_{W}$

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream (semi-solid)

4. Clinical particulars

4.1 Therapeutic indications

Gentamicin in Drugent® -HC Cream is indicated for topical treatment of skin infections due to susceptible organisms while hydrocortisone is indicated in inflammatory disorders of the skin such as contact eczema, atopic eczema, psoriasis seborrhoeal eczema, intertrigo, and non specific prupritis.

Drugent® -HC is indicated for local treatment of acute topical infections of the skin furunculi, abscess, impetigo, intertrigo, secondary infected eczema, as well as inflammatory skin conditions with secondary bacterial infections.

4.2 Posology

Adults, the elderly and the paediatric population

Method of administration

The cream should be sparingly rubbed to the affected parts of the skin two to three times daily.

4.3 Contraindications

Drugent® -HC is contraindicated in individuals who have been shown to be hypersensitive to Gentamicin, or any of the constituents. Usage on large skin leison should be avoided because of possible systemic toxic effects. Prolong use may also result in overgrowth of non susceptible micro organisms. It should not be applied with an occlusive dressing to large areas of the body, in the presence of infections, ulcers of the leg, long term use should also be avoided and hypersensitivity to corticosteroids.

4.4 Special warnings and precautions for use

Long-term continuous topical therapy should be avoided. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms. Cross sensitivity with other aminoglycoside antibiotics may occur.

In severe infections, topical use of this medicine should be supplemented with appropriate systemic antibiotic treatment.

The product is a topical preparation hence in the event of excessive topical application resulting into redening of the skin, itching or burning sensation, the affected area should be washed with soap and water. Any other systemic effects should be treated symptomatically.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Paediatric population

In infants there is a theoretical risk that sufficient steroid may be absorbed to cause adrenal suppression.

4.5 Interaction with other medicinal products and other forms of interaction

None relevant to topical use.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety for use in pregnancy has not been established. Topical administration of any corticosteroid to pregnant animals can cause abnormalities of foetal development. This medicine should only be used in pregnancy when considered essential by the physician, after careful assessment of the potential risks and benefits.

Breast-feeding

Safety for use in lactation has not been established. This medicine should only be used in lactation when considered essential by the physician, after careful assessment of the potential risks and benefits.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

In the event of irritation, sensitization or super-infection, treatment with Drugent HC Cream should be discontinued and appropriate therapy instituted. The undesirable effects listed below have been reported at the following frequency:

Not known (cannot be estimated from available data)

System organ class	Frequency	Undesirable effects
Skin and subcutaneous tissue disorders	Not known	-Burning sensation - Stinging -Itching (pruritus): -Dermatitis.

4.9 Overdose

Not applicable.

5. PHARMACOLOGICALPROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinfectives ATC code: S03AA

Mechanism of action:

Gentamicin is mixture of antibiotic substances produced by the growth of micromonospora purpurea. It is a bactericidal antibiotic which acts by inhibiting protein synthesis. It has greater antibacterial activity than streptomycin, neomycin or kanamycin.

Gentamicin exerts a number of effects on cells of susceptible bacteria. It affects the integrity of the plasma membrane and the metabolism of RNA, but it's most important effect is inhibition of protein synthesis at the level of the 30s ribosomal subunit.

Corticosteroids, such as hydrocortisone acetate, are used in pharmacological doses for their anti-inflammatory and immuno-suppressant glucocorticoid properties which suppress the clinical manifestation of disease in a wide range of disorders.

5.2 Pharmacokinetic properties

Absorption:

Topical application of gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µg/ml.

Gentamicin is 70-85% bound to plasma albumin following administration. Effective plasma concentration is 4 - 8ug/ml

The volume of distribution ($^{V}_{D}$) is 0.3 1/kg

Hydrocortisone acetate is not absorbed through the skin as rapidly as hydrocortisone and therefore has a prolonged action. Some is absorbed systemically, where greater than 90% is protein bound.

Elimination:

> 90% Gentamicin is excreted unchanged in the urine by glomerular filtration.

$T_{½}$ = 2 - 3 hours in individuals with normal kidney function, but can be increased in cases of renal insufficiency.

The elimination rate constant is; 0.02 Hr^{-1} for anuric patients* 0.30 Hr^{-1} normal

*Therefore in those with anuria care must be exercised.

> 70% hydrocortisone acetate is metabolised by the liver. The metabolites are excreted in the urine. Plasma $T_{½}$ = 1½ hours.

5.3 Preclinical safety data

Subcutaneous administration of betamethasone valerate to mice or rats at doses ≥0.1 mg/kg/day or rabbits at doses ≥12 micrograms/kg/day during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

The effect on fertility of betamethasone valerate has not been evaluated in animals.

6 PHARMACEUTICALPARTICULARS

6.1 List of excipients

Liquid Paraffin (Heavy)
Ceto-stearyl Alcohol
Stearic Acid
Cetomacrogol 1000
Propylene Glycol
Benzyl Alcohol
Purified Water

6.2 Incompatibilities

None have been reported or are known

6.3 Shelflife

48 Months

6.4 Special precautions forstorage

Store below 30^{o}C in tight container protected from light and moisture.

6.5 Nature and contents of container and special equipment for use, administration or implantation

Drugent® -HC Cream is presented in 20g printed aluminium tube with a screw cap packed in hardboard carton with leaflet enclosed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 APPLICANT/MANUFACTURER

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