CLINDOXYL® GEL

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

CLINDOXYL® GEL

COMPOSITION:

Each 100 g contains:

Clindamycin phosphate equivalent to clindamycin 1,00 g and hydrous benzoyl peroxide equivalent to anhydrous benzoyl peroxide 5,00 g.

PHARMACOLOGICAL CLASSIFICATION:

A 13.11 Acne preparations

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Clindamycin is a lincosamide antibiotic with bacteriostatic action against Gram-positive aerobes and a wide range of anaerobic bacteria. Lincosamides such as clindamycin bind to the 23S subunit of the bacterial ribosome and inhibit the early stages of protein synthesis. The action of clindamycin is predominantly bacteriostatic although high concentrations may be slowly bactericidal against sensitive strains. Although clindamycin phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to the antibacterial active clindamycin.

Clindamycin activity has been demonstrated against most strains of *Propionibacterium acnes.* Clindamycin *in vitro* inhibits all *P acnes* cultures tested (MIC 0,4 µg/ml). Benzoyl peroxide is keratolytic and an oxidising agent acting against *Propionibacterium acnes,* the organism implicated in acne vulgaris. Furthermore it is sebostatic, counteracting the excessive sebum production associated with acne.

Pharmacokinetic properties:

In a maximised percutaneous absorption study the mean plasma clindamycin levels during a four week dosing period for CLINDOXYL GEL were negligible (0,043 % of applied dose).

The presence of benzoyl peroxide in the formulation did not have an effect on the percutaneous absorption of clindamycin.

Radio-labelled studies have shown that absorption of benzoyl peroxide through the skin can only occur following its conversion to benzoic acid. Benzoic acid is mostly conjugated to form hippuric acid which is excreted via the kidneys.

INDICATIONS:

CLINDOXYL GEL is indicated in the treatment of mild to moderate acne vulgaris, particularly inflammatory lesions in adolescents and adults.

CONTRA-INDICATIONS:

CLINDOXYL GEL should not be used in patients with known hypersensitivity to clindamycin, lincomycin, benzoyl peroxide or any of the excipients in the formulation.

WARNINGS AND SPECIAL PRECAUTIONS:

Contact with the mouth, eyes, skin and mucous membranes and with abraded or eczematous skin should be avoided. Application to sensitive areas of skin should be

made with caution. In the event of accidental contact with the eyes, bathe with copious amounts of water.

The product may bleach hair or coloured fabrics.

It is recommended that exposure to sun or sunlamps be minimised.

Patients should be advised that, in some cases, 4-6 weeks of treatment may be required before the full therapeutic effect is observed.

It should be used with caution in atopic patients, in whom further skin drying may occur.

The frequency of application should be reduced if excessive irritation or dryness develops.

With long term use of CLINDOXYL GEL resistance may occur. Cross resistance may occur with other antibiotics such as lincomycin and erythromycin when using antibiotic monotherapy.

There have been isolated reports of pseudomembraneous colitis or diarrhoea due to other topical treatments containing clindamycin.

INTERACTIONS:

Concomitant topical antibiotics, medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect and products with high concentrations of alcohol and or astringents should be used with caution as a cumulative irritant effect may occur.

Simultaneous application of CLINDOXYL GEL and topical acne preparations containing vitamin A derivatives should be avoided.

Potential synergism exists between clindamycin and gentamycin.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

For application to the skin. For external use only.

Adults and adolescents:

Apply once daily in the evening, to the affected areas after the skin has been thoroughly washed, rinsed with warm water and gently patted dry.

Use in children:

The safety and efficacy of CLINDOXYL GEL has not been established in prepubescent children (under 12 years of age).

Treatment with CLINDOXYL GEL should not exceed more than 12 weeks of continuous use.

SIDE EFFECTS:

CLINDOXYL GEL may cause erythema, peeling, dryness and pruritus at the site of application. Uncommonly, paraesthesia, worsening of acne and contact dermatitis can occur.

Reported frequency in clinical trials are:

Very common (>1/10): Erythema; peeling; dryness

Common (>1/100, <1/10): Burning; pruritus

Uncommon (>1/1000, <1/100): Paraesthesia; worsening of acne.

There have been isolated reports of pseudomembraneous colitis or diarrhoea due to other topical treatments containing clindamycin.

In the post marketing environment there have been isolated instances of allergic reactions which can be sudden and severe.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No case of overdose has been reported.

IDENTIFICATION:

A white to slightly yellow homogenous gel.

PRESENTATION:

Membrane-sealed aluminium tubes fitted with a white polyethylene screw cap containing 25 g of gel presented in a carton.

STORAGE INSTRUCTIONS:

Store in a refrigerator between +2 °C and +8 °C.

Do not freeze.

Storage conditions after dispensing: Store at or below 25 °C. Use within 2 months after dispensing.

Keep well closed.

Keep out of reach of children.

REGISTRATION NUMBER:

42/13.11/0441

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THE PACKAGE INSERT:

1 March 2013

Update History:

28-05-2008: PI aligned to 11-04-2008 Clinical Committee recommendation (CLINICAL UNIT; N2/6/2(420441); Item No. N/A; CCC 2/08)

26-01-2009: Compliant PI aligned to 04-12-2008 Clinical Committee recommendation (CLINICAL UNIT; N2/6/2(420441); Item No. N/A; CCC 5/08)

18/07/2011: PI aligned to 18-03-2011 P&A Committee recommendations (Pharmaceutical Sect; N2/6/2(420441) recommendations 1.2; 1.3; 1.4 & 1.5.

27/09/2011: Transfer of Applicant to GSK

Registered 1 March 2013

14.10.2013 – GDS02 submitted

28.05.2015 – Notification of implementation of Reg 9 and 10