Summary of Product Characteristics
PIP OFF GEL

1. NAME OF THE MEDICINAL PRODUCT:

Pip Off Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each tube contains

Clindamycin Phosphate USP equivalent to Clindamycin 1.00 % w/w

3. PHARMACEUTICAL FORM:

Gel.

A light pink coloured smooth gel.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Pip Off Gel is indicated for the topical treatment of mild to moderate acne vulgaris.

4.2 Posology and method of administration:

Apply a thin film of Pip Off Gel once daily to the affected area Or as directed by the physician.

Patient response should be reviewed after 6-8 weeks of treatment and the duration of treatment should be limited to 12 weeks.

4.3 Contraindications:

Pip Off Gel is contraindicated in patients with hypersensitivity or allergy to Clindamycin or any of the excipients of the product.

4.4 Special precautions and warnings:

Pip Off Gel has an alcohol base which may cause burning and irritation of eyes. In case of accidental contact with sensitive surfaces such as eye, abraded skin, mucous membrane rinse the area with cool tap water.

Prolonged use of clindamycin may cause resistance and/or overgrowth of non-susceptible bacteria or fungi although this is a rare occurrence. Cross resistance may occur with other antibiotics such as lincomycin and erythromycin.

Pip Off Gel is for eternal use only.

4.5 Interactions with other medicinal products and other forms of interaction:

Concomitant use of non-depolarizing muscle relaxant such as vecuronium or succinylcholine should be avoided since, Clindamycin may increase the risk of their side effects.

Use of Erythromycin with Clindamycin may decrease the effectiveness of Clindamycin.

4.6 Pregnancy and Lactation:

For clindamycin applied cutaneously no clinical data on exposed pregnancies are available. Data on a limited number of pregnancies exposed to clindamycin administered by other routes indicate no adverse effects on pregnancy or on the health of the fetus/newborn child.

Orally and parenterally administered clindamycin has been reported to appear in breast milk. It is not known whether clindamycin is excreted in human milk following topical use. As a general rule, patients should not breastfeed while taking a drug since many drugs are excreted in human milk.

For use during pregnancy and lactation, benefit and possible risks have to be weighed carefully against each other. Sensitisation and diarrhoea cannot be ruled out in nursed infants.

4.7 Effects on ability to drive and use machines:

None known

4.8 Undesirable effects:

Pip Off Gel can cause skin dryness, erythema, skin burning, irritation around eyes, acne exacerbations and pruritis.

Clindamycin Gel should not be applied in skin abrasions or cuts since higher absorption of drug may take place which may lead to dizziness, headache, diarrhea, stomach upset and nausea.

4.9 Overdose:

It is not expected that overdose would occur in normal use. Irritant dermatitis may occur when excessive quantities are applied. The use of a suitable moisturiser may be of benefit in these cases. No systemic side effects usually observed with topical use.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Pip-Off gel contains Clindamycin phosphate and anti-infective for treatment of acne. Clindamycin phosphate is hydrolysed in the skin to the active constituent clindamycin. Clindamycin is a lincosamide antibiotic with primarily bacteriostatic action against Gram positive aerobes and wide range of anaerobic bacteria.

When clindamycin phosphate is applied cutaneously, clindamycin is active against most strains of Propionibacterium (P. acnes). It thus reduces the number of surface and follicular P.acnes, one of the aetiological factors of the disease.

5.2 Pharmacokinetic properties:

Minimum absorption of Clindamycin occurs through systemic absorption of clindamycin. An in vitro study with Clindamycin with normal human skin has shown the in vitro absorption of radiolabelled clindamycin phosphate is found to be less than 5% of the applied dose.

Clindamycin phosphate is metabolised to the parent drug in the skin and clindamycin itself is primarily metabolised in the liver via N-demethylation, sulphoxidation and hydrolysis and predominantly excreted in the bile.

5.3 Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients:

Sodium Methyl Paraben BP, Sodium Propyl Paraben BP, Titanium Dioxide BP, Red Iron Oxide IHS, Carbopol 940 USP, Propylene Glycol BP, Isopropyl Alcohol BP, Triethanolamine BP, Fragrance-Lavender IHS, Purified Water.

6.2 Incompatibilities:

Not applicable

6.3 Shelf life:

2 years

6.4 Special precautions for storage:

Do not store above 30^{o}C.

Do not refrigerate and keep out of reach of children.

6.5 Nature and contents of container:

25g of printed lami tube packed in a carton along with a leaflet.

7. Manufactured at:

Gopaldas Visram & Co.Ltd.

A-590/591-T.T.C. Industrial Area, M.I.D.C, Mahape, Navi Mumbai, India.

8. MARKETING AUTHORISATION HOLDER:

Bliss GVS Pharma Ltd.

102, Hyde park, Saki Vihar Road, Andheri (East), Mumbai - 400 072, INDIA.

9. DATE OF AUTHORISATION/RENEWAL:

07.06.2014