BERLIN DEEP HEAT CREAM

(Diclofenac Diethylamine, Methyl Salicylate, Menthol & Linseed Oil Gel)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the Medicinal Product

Berlin Deep Heat Cream

(Diclofenac Diethylamine, Methyl Salicylate, Menthol & Linseed Oil Gel)

2. Qualitative and Quantitative Composition

Composition

Linseed Oil BP 3.0% w/w

Diclofenac Diethylamine BP 1.16 % w/w

Eq to Diclofenac Sodium 1.0 % w/w

Menthol BP 5.0 % w/w

Methyl Salicylate BP 10.0 % w/w

Benzyl Alcohol BP 1.0% w/w (as preservative)

Gel Base q.s.

3. Pharmaceutical Form

Gel

4. Clinical Particulars

4.1 Therapeutic indications

For the local symptomatic relief of pain and inflammation in:

- trauma of the tendons, ligaments, muscles and joints, eg due to sprains, strains and bruises
- localised forms of soft tissue rheumatism

It is recommended that the treatment be reviewed after 14 days in these indications. For the treatment of osteoarthritis of superficial joints such as the knee. In the treatment of osteoarthritis, therapy should be reviewed after 4 weeks.

4.2 Posology and method of administration Dosage and Administration

Adults: Diclofenac Gel should be rubbed gently into the skin. Depending on the size of the affected site to be treated 2-4g (a circular shaped mass approximately 2.0-2.5cm in diameter) should be applied 3 - 4 times a daily.

After application, the hands should be washed unless they are the site being treated.

Use in the elderly: The usual adult dosage may be used.

Children and adolescents: There are insufficient data on efficacy and safety available for the children and adolescents below 14 years of age In children aged 14 years and

over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

Diclofenac Gel is suitable for the transmission of ultrasound and may be used as a couplant in combination with ultrasound therapy. If large areas of the body are covered with gel, systemic absorption will be greater and the risk of side-effects increased, especially if the therapy is used frequently.

4.3 Contraindications

- Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute
- rhinitis are precipitated by acetylsalicylic acid (aspirin) or other non- steroidal antiinflammatory
- drugs (NSAIDs).
- Hypersensitivity to diclofenac or any of the excipients
- Third trimester of pregnancy.
- The use in children and adolescents aged less than 14 years is contraindicated.

4.4 Special warning and special precaution for use

The possibility of systemic adverse events from application of Diclofenac Gel cannot beexcluded if the preparation is used on large areas of skin and over a prolonged period.

Diclofenac Gel contains propylene glycol, which may cause mild, localised skin irritation in some people.

Concomitant use of oral NSAID's should be cautioned as the incidence of untoward effects,

particularly systemic side effects, may increase.

Diclofenac Gel should not be co-administered with other products containing diclofenac.

Diclofenac Gel should be applied only to intact, non-diseased skin and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes, and should not be ingested.

Discontinue the treatment if a skin rash develops after applying the product. Diclofenac Gel can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Some possibility of gastro-intestinal bleeding in those with a significant history of this condition has been reported in isolated cases.

4.5 Interaction with other medicinal products and form of interaction

Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely. There are no known interactions with Diclofenac Gel but for a list of interactions known with oral diclofenac the data sheet for oral dosage forms should be consulted.

4.6 Pregnancy and lactation

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation wasincreased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryofetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis; The mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Lactation

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at

therapeutic doses of Diclofenac Gel no effects on the suckling child are anticipated. Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, Diclofenac Gel should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time

4.7 Effects on ability to drive and use machines

Cutaneous application of Diclofenac Gel has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: very common (> 1/10); common ≥(1/100, <1/10); uncommon ≥(1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (<1/10,000), not known: cannot be estimated from the available data. Although less likely with the topical administration, some side effects normally associated with systemically administered diclofenac may also occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Signs and symptoms

The low systemic absorption of Diclofenac Gel renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if Diclofenac Gel is inadvertently ingested (1 tube of 100g contains the equivalent of 1000mg of diclofenac sodium). In the event of accidental ingestion, resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with non- steroidal anti-inflammatory medicines should be used. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion

Treatment

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from Voltarol overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal

irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain, anti inflammatory preparations, non-steroids for topical use (ATC code M02A A15)

Diclofenac Gel is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Due to an aqueous-alcoholic base the gel exerts a soothing and cooling effect.

5.2 Pharmacokinetic properties

When Diclofenac Gel is applied locally, the active substance is absorbed through the skin. In healthy volunteers approximately 6% of the dose applied is absorbed, as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients confirm that diclofenac penetrates inflamed areas following local application of Diclofenac Gel.

5.3 Preclinical Studies

None known.

6.0 PHARMACEUTICAL EXCIPIENTS

6.1 List of excipients

1. Benzyl Alcohol BP
2. Carbopol-934 BP
3. Triethanolamine BP
4. Disodium EDTA BP
5. Citric Acid BP
6. Butylated Hydroxytoluene BP
7. Propylene Glycol BP
8. Polysorbate – 80 BP
9. Isopropyl Alcohol BP
10. Purified water BP

6.2 Incompatibilities

Not applicable

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6.3 Shelf life

36 months.

6.4 Special precaution for storage

Store at temperature below 30°C. Protect from light.

6.5 Nature contents of container

30 gm Lami tube with screw capped in a carton

6.6 Instruction for use handling and disposal

Keep out of reach of children.

7. Manufacturer name

Alpa Laboratories Limited
33/2 A.B Road, Pigdamber, Indore (MP)
Pin Code- 453446
+91 731 4294567
+91 731 4294444

8. Marketing Authority

BERLIN PHARMA AND HEALTH CARE
LIMITED,
No 42, Comfort Oboh Kiri Kiri Industry
Area Apapa- Lagos, Nigeria