Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Pengo Gel

2. Qualitative and quantitative composition

Each gram of gel contains 10 mg of diclofenac sodium (equivalent to 11.6 mg of diclofenac diethylamine).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Gel,

Clear translucent gel

4. Clinical particulars

4.1 Therapeutic indications

Pengo Gel is indicated in adults and adolescents aged 14 years and over as anti-inflammatory and analgesic agent in the treatment of:

- mild to moderate muscle pain;

- contusions;

- post-traumatic pain.

4.2 Posology and method of administration

Posology

Adults and adolescents aged 14 years and over

Apply thin layers of Diclofenac 1% Gel in the affected area, 3-4 times daily according to the need of the situation (about 2-4 g, quantity as big as a cherry or a walnut) and rub gently.

The treatment duration depends on the indications and the patient's response to the treatment. It is recommended that the treatment should be evaluated 7 days after its beginning.

In adolescents aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patients/parents of the adolescent is/are advised to consult a doctor.

Diclofenac 1% Gel can be used as additional treatment to the oral administration of non-steroidal anti-inflammatory drugs.

Children and adolescents aged below 14 years

There are insufficient data on efficacy and safety available for the children and adolescents below 14 years of age.

Hepatic and renal impairment

No dosage adjustment is required in patients with hepatic impairment.

Diclofenac 1% Gel is contraindicated in patients with renal impairment.

Elderly

The usual adult dosage may be used.

Method of administration

Cutaneous use.

Apply on healthy skin only.

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

Diclofenac 1% Gel can be used as additional treatment to the oral administration of non-steroidal anti-inflammatory drugs.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

- Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti- inflammatory drugs (NSAIDs).

- The use in children and adolescents aged less than 14 years is contraindicated.

- Third trimester of pregnancy.

- Patients with renal impairment.

4.4 Special warnings and precautions for use

The occurrence of systemic undesirable effects with the topical use of diclofenac is low when compared with the frequency of undesirable effects with the oral use of diclofenac.

The possibility of systemic adverse events from application of topical diclofenac cannot be excluded if the preparation is used on large areas of skin and over a prolonged period.

Cutaneous safety of NSAIDs: Serious skin reactions, some of them fatal, have been reported very rarely, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, associated with the administration of NSAIDs. Apparently the risk of occurrence of these reactions is higher at the beginning of the treatment and in most cases these reactions are manifested during the first month of treatment. Concomitant use of oral NSAID's should be cautioned as the incidence of untoward effects, particularly systemic side effects, may increase.

Diclofenac 1% Gel should be discontinued at the first signs of rash, mucosal injuries or other hypersensitivity manifestations.

Topical diclofenac 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.

The area treated with Diclofenac 1% Gel should not be exposed to sunlight.

Topical diclofenac can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Diclofenac 1% Gel also contains propylene glycol which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Diuretics, Angiotensin Converting Enzyme Inhibitors (ACE inhibitors) and Angiotensin II Antagonists (AAII): NSAIDs may decrease the effectiveness of diuretics and other antihypertensive medicinal products. In some patients with impaired renal function (e.g., dehydrated patients or elderly with impaired renal function) the co-administration of an ACEI or AIIA and cyclooxygenase inhibitor agents may result in the progression of renal function deterioration, including the possibility of acute renal insufficiency, which is usually reversible. The occurrence of these interactions should be considered in patients applying diclofenac, particularly if in large areas of the skin and for prolonged periods, in combination with ACEI or AIIA. Consequently, this drug combination should be used with caution, especially in elderly patients. Patients should be properly hydrated and the need to monitor the renal function after the beginning of the concomitant therapy and periodically thereafter should be analysed.

Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy

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/foetal 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 was increased 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 embryo-foetal 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 foetus to:

o cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);

o renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

• the mother and the neonate, at the end of pregnancy, to:

o possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.

o inhibition of uterine contractions resulting in delayed or prolonged labour.

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

Breast-feeding

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of topical diclofenac 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, this medicinal product 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 topical diclofenac has no or negligible 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.

Table 1

Immune system disorder:

Very rare: Hypersensitivity (including urticaria), angioneurotic oedema.

Infections and infestations:

Very rare: Rash pustular.

Respiratory, thoracic and mediastinal disorders

Very rare: Asthma.

Skin and subcutaneous tissue disorders

Common: Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus

Rare: Dermatitis bullous

Very rare: Photosensitivity reaction

Not known: Burning sensation at the application site

Dry skin

Although less likely with the topical administration, some side effects normally associated with systemically administered diclofenac may also occur.

The prolonged use of diclofenac in a relatively extensive area can cause systemic side effects such as nausea, vomiting, diarrhoea or epigastric pain.

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. Healthcare professionals are asked to report any suspected adverse reactions via PvERS Scheme at www.pharmacyboardkenya.org.

4.9 Overdose

The low systemic absorption of topical diclofenac renders overdose very unlikely.

However, undesirable effects similar to those observed following an overdose of Diclofenac tablets can be expected if Topical diclofenac is inadvertently ingested (1 tube of 100 g contains the equivalent of 1,000 mg 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain, Antiinflammatory preparations, non-steroids for topical use,

ATC code: M02AA15

Diclofenac is a phenylacetic acid derivative. It leads to the inhibition of cyclooxygenase activity, which then leads to the inhibition of the synthesis of prostaglandin and other mediators of inflammation. Diclofenac acts as anti- inflammatory and analgesic agent in the treatment of topical symptoms of rheumatic and non-rheumatic pains of the locomotor apparatus.

5.2 Pharmacokinetic properties

Absorption

After topical application, diclofenac is well-absorbed into the subcutaneous layers of the skin. In healthy volunteers, the maximum level of diclofenac after a 7.5 g dose of 1% of concentration was, on average, approximately 3.9

ng/ml. After several days of treatment, the concentration on skin and soft tissues of patients with arthrosis reached values 30 to 40 times higher than the ones from plasma. The diclofenac absorption in the 1% concentration applied on the healthy skin reached 6 to 7% in healthy individuals.

Distribution

The diclofenac concentration was measured on plasma and tissue and synovial fluid after topical administration in the hands and knees joints. Maximum plasma concentration was about 100 times lower than after oral administration. Diclofenac binds 99.7% to plasma proteins, mainly albumin (99.5%).

Biotransformation

Biotransformation of diclofenac involves partly glucuronidation of the intact molecule, and mainly single and multiple hydroxylations, most of which are converted to glucuronide conjugates (hydroxyl-gluconates). The main metabolite is 4-hydroxy-diclofenac (30%-40%). All the metabolites are biologically active, but to a much smaller extent than diclofenac.

Elimination

Diclofenac and its metabolites are excreted mainly in the urine. Total clearance of diclofenac from plasma is 263 ± 56 ml/min. The terminal plasma half-life is of 1-2 hours. Its metabolites have similar plasma half-lives of 1-3 hours. Approximately 60% of the dose administered is eliminated in the urine in the form of metabolites, only 1% in the form of diclofenac. The remaining is eliminated as metabolites by bile and in faeces.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity,carcinogenic potential and reproductive toxicity, at the intended therapeutic doses.

At high systemic levels of diclofenac, not observed following topical application of Diclofenac 1% Gel, toxicity of diclofenac took the form mainly of lesions and ulcers in the gastro-intestinal tract. Increased duration of gestation, dystocia and increased resorptions were observed at maternally toxic doses.

6. Pharmaceutical particulars

6.1 List of excipients

Carbomer BP, Propylene Glycol BP, Rectified Spirit (Alcohol 96%) BP, Polyethylene Glycol 400 BP, Glycerine BP, Sodium Sulfite BP, Perfume Lavender IH and Purified Water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a dry place below 30°C

Protect from light

Keep all medicines out of reach of children.

6.5 Nature and contents of container

Low density polyethylene (LDPE) or aluminium tube with cap.

Pack sizes: 20g.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder

Dinlas Pharma (Africa) Limited

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P.O Box 22661-00505

Nairobi-Kenya

8. Marketing authorization number(s)

CTD9513

9. Date of first authorization/renewal of the authorization

Date of first authorization: 18/09/2023

Renewal of authorization: 18/09/2028

10. Date of revision of the text

06/05/2025