Summary of Product Characteristics

1. Name of the medicinal product

Fast Act Gel.

2. Qualitative and quantitative composition

Contains: Diclofenac Diethylamine1.16%w/w and Methyl Salicylate 10.0%w/w.

3.0 Pharmaceutical form:

Gel

A white coloured, non –gritty gel, free from visible evidence of contamination.

4.0 Clinical particulars

4.1Therapeutic indications

Fast-Act gel is used for localized symptomatic relief of pain and inflammation in conditions such as; Trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains, backache, joint pain and muscular pain and Localized forms of soft tissue rheumatism.

4.2 Posology and method of administration:

Topical administration (For external application only).

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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 anti-inflammatory drugs (NSAIDs).
Hypersensitivity to the active or any of the excipients. In third trimester of pregnancy, do not apply to skin abrasions and do not apply to irritated skin.
Contraindicated in patients who are hypersensitive to salicylates or to any other ingredient in the preparation. If irritation develops, use of the product should be discontinued.

4.4 Special warnings and precautions for use

Fast act gel contains propylene glycol, which may cause mild, localized 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. It should not be co-administered with other products containing Diclofenac diethylamine and methyl salicylate.
Fast act 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. Fast act gel can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing. Keep away from eyes and sensitive areas. If symptoms persist consult a doctor. Wash hands thoroughly after use. Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

Since systemic absorption of Diclofenac from a topical application is very low such interactions are very unlikely. There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin. Menthol has also been reported to interact with warfarin (when taken orally), decreasing its effectiveness.

4.6. Pregnancy and lactation

The systemic concentration of Diclofenac is lower after topical administration. Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. There is no, or inadequate evidence of safety in human pregnancy or lactation for the use of methyl salicylate.

4.7Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

Common adverse effects include photosensitivity and hypersensitivity to the ingredients. Salicylate intoxication can occur following ingestion or topical application of methyl salicylate. Others include dermatitis or eczema, hypersensitivity reactions characterized by urticaria, flushing and headache. Skin irritation may also occur.

4.9 Overdose.

When used externally as directed, overdose is unlikely. However, symptoms of systemic salicylate poisoning have been reported after the application of salicylates to large areas of skin or for prolonged periods. Salicyclism may also occur in the unlikely event of large quantities being ingested. Common features include vomiting, dehydration, tinnitus, vertigo, deafness, and sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation.

Activated charcoal may be administered if significant quantities have been ingested within an hour of presentation. Haemodialysis is the treatment of choice for severe poisoning

5. 0 Pharmacological properties

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: Anti-inflammatory preparations, non-steroids for topical use, combinations.

ATC code: M02AA99.

Pharmacology:

Prostaglandins are physiological mediators with wide-ranging pharmacological properties, which include their action on spinal neurons which causes pain.Cyclo-oxygenases play an important role in the biosynthesis of prostaglandins.

Methyl Salicylate and Diclofenac diethylamine inhibit cyclo-oxygenase-1 (COX-1) and cyclo-oxygenase-2 (COX-2). Inhibition of COX-2 is associated with anti-inflammatory activity.

5.2 Pharmacokinetic properties

Diclofenac is absorbed topically. Diclofenac penetrates synovial fluid where concentrations may persist even when plasma concentrations fall; small amounts are distributed into breast milk. The terminal plasma half-life is about 1 to 2 hours.

Methyl salicylate may be absorbed through intact skin. Percutaneous absorption is enhanced by exercise, heat, occlusion, or disruption of the integrity of the skin. The amount absorbed will also be increased by application to large areas of skin. Methyl salicylate is extensively metabolized to salicylic acid in the dermal and subcutaneous tissues following topical administration.

5.3 Pre-clinical safety data.

No additional data of relevance

6.0 Pharmaceutical particulars

6.1 List of excipients

Menthol
Linseed oil
Benzyl alcohol
Carbomer
Propylene glycol
Cetomacrogol 1000
Sodium hydroxide
Isopropyl alcohol
Diethylamine
Purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 Months from the date of manufacture.

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
20gm printed collapsible aluminium tube with a white screw cap packed in a unit box along with a literature insert.
6.6 Special precautions for disposal and other handling
None applicable.

7. Registrant:
Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka,
P.O Box 16633-00620,
Nairobi, Kenya.

8. Manufacturer:
Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka,
P.O Box 16633-00620,
Nairobi, Kenya.
9.Legal category: Pharmacy Only

10.Date of revision of the text:
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