SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fiery Jack Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycol Salicylate BP 5.00 % w/w, Diethylamine Salicylate BP 5.00 % w/w, Capsicum Oleoresin BPC 1.25 % w/w, Methyl Nicotinate BP 1.00% w/w.

3 PHARMACEUTICAL FORM

Cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Symptomatic relief of muscular pain and stiffness including Sciatica, Lumbago, Fibrositis and Rheumatic pain.

4.2 Posology and method of administration
One or two applications per day should suffice to give relief. Not recommended for children under 12 years.

4.3 Contraindications
Not to be used on patients allergic or sensitive to Salicylates. Not to be used on broken skin.
4.4 **Special warnings and precautions for use**
For external use only.
Consult a Doctor if pain persists.
Keep out of reach of children.

4.5 **Interaction with other medicinal products and other forms of interaction**
None stated.

4.6 **Fertility, Pregnancy and lactation**
None stated.

4.7 **Effects on ability to drive and use machines**
None stated.

4.8 **Undesirable effects**
None stated.

4.9 **Overdose**
None stated.

5 **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**
Glycol Salicylate: is an ingredient of a number of rubifacient creams.

Diethylamine Salicylate: is used topically at concentration of 5 or 10% in creams for rheumatic or muscular pain.

Capsicum Oleoresin: Capsicum is mainly used as an external counter irritant.
The Oleoresin is very irritant. The active ingredient Capsaicin has local analgesic properties.

Methyl Nicotinate: is used in ointments and creams for topical application as a rubefacient for the relief of pain and muscular rheumatism, lumbago and fibrositis.

5.2 Pharmacokinetic properties
Not applicable.

5.3 Preclinical safety data
Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sebase, Emulsifying Wax, Euxyl K100, Water.

6.2 Incompatibilities
None stated.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Dry, frost free conditions.

6.5 Nature and contents of container
Aluminium printed tube containing 35gm
6.6 Special precautions for disposal
Not applicable

7 MARKETING AUTHORISATION HOLDER
Optima Consumer Health Limited
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Brackenbeck road
Bradford
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8 MARKETING AUTHORISATION NUMBER(S)
PL 40575/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
02/03/2006

10 DATE OF REVISION OF THE TEXT
20/09/2012