Summary of Product Characteristics (SPC)

1. Name of the medicinal product
VOLIGESIC PLUS GEL (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel)

1.1 *International Non-Proprietary Name (INN)*
Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel

1.2 *Strength*
Diclofenac Diethylamine BP 1.16% w/w
Linseed Oil BP 3.0% w/w
Methyl Salicylate BP 10.0% w/w
Menthol USP 5.0% w/w

1.3 *Pharmaceutical form*
Topical Gel

2. Qualitative and quantitative composition

Diclofenac Diethylamine BP	1.16% w/w
Eq. to Diclofenac Sodium	1% w/w
Linseed Oil BP	3% w/w
Methyl Salicylate BP	10% w/w
Menthol USP	5% w/w
Benzyl Alcohol BP (As Preservative)	1% w/w
Gel Base	q.s.

3. Pharmaceutical form
Topical Gel
White coloured semi-solid mass filled in printed laminated tube.

4. Clinical particulars
4.1 Therapeutic indications
- Diseases of the locomotor system: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis, osteoarthrosis of peripheral joints and spinal column, osteochondrosis with radicular syndrome, sciatica);
- Rheumatic damage to soft tissues (tenosynovitis, bursitis) ;
- Muscular pain of rheumatic or non-rheumatic origin;
- Traumatic damage to soft tissues (due to sprains, bruises).

4.2 Posology and method of administration
For external use.

Adults and children over 12 years: apply the formulation on the skin 3-4 times in a day and rub in gently. The quantity of formulation to be used depends upon the size of the painful area. A single dose is 2-4 g (4-8 cm when the tube neck is fully open). Children from 6 to 12 years old to apply no more than 2 times a day, a single dose of 2 grams.
The duration of treatment without consulting a physician should not exceed 10 days. The possibility of a long-term use of medicine the doctor decides individually.

Method of administration
For external use.

4.3 Contraindications
Hypersensitivity to diclofenac, methyl salicylate or other components of the formulation, acetylsalicylic acid or other NSAIDs, aspirin "asthma", pregnancy (third trimester), lactation period, children below 6 years, broken skin.

4.4 Special warnings and precautions for use
Severe cutaneous adverse reactions

This formulation should be applied only on unbroken skin and not on open wounds. Occlusive dressing is not recommended after application. Care should be taken to avoid contact with the eyes and mucous membranes.
Use with caution in: severe disorders of the liver and kidney functions, bronchial asthma, pregnancy (first and second trimesters), elderly patients.
.

4.5 Interaction with other medicinal products and other forms of interaction
Diclofenac may potentiate the action of drugs which induce photo sensitisation. Clinically significant interactions with other drugs have not been reported.

4.6 Pregnancy and Lactation
This formulation should not be used in the third trimester of pregnancy. The question of use of the drug in first and second trimesters of pregnancy is solved individually. Due to the lack of experience of using drug during lactation, its use in this period is not recommended.

4.7 Effects on ability to drive and use machines
The drug does not adversely affect the ability to drive vehicles and other potentially dangerous machinery.

4.8 Undesirable effects
Local reactions: eczema, photosensitisation, contact dermatitis (itching, redness, oedema of treated area of skin, papules, vesicles, peeling).

Systemic reactions: generalised skin rash, allergic reactions (urticaria, Quincke's (angioneurotic) oedema, bronchospastic reactions).

4.9 Overdose

The very low systemic absorption of the active components of the formulation when used externally makes overdose practically impossible. In case of accidental ingestion may develop systemic side effects. Treatment for ingestion: gastric lavage, induction of emesis, activated charcoal, forced diuresis, symptomatic therapy. Dialysis is ineffective because of the high degree of binding of diclofenac to plasma proteins (approximately 99%).

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drugs (NSAIDs)., ATC Code: M01AB55

The pharmacological action of the formulation is based on the ingredients. It has a local analgesic, antiinflammatory and anti-o edematous action. Diclofenac sodium and methyl salicylate are non-steroidal antiinflammatory drugs with a pharmacological action based on the ability to inhibit synthesis of prostaglandins. When used locally, diclofenac and methyl salicylate are rapidly absorbed, penetrate into the subcutaneous fat, muscular tissue and joint capsule, reduce pain and inflammation in the joints, morning stiffness and swelling of joints, facilitate increase in the extent of movements. The main component of linseed oil is α-linolenic acid which has an anti-inflammatory action. Menthol induces irritation of nerve endings and has a local distracting and mild analgesic action, besides inducing a cooling sensation.

5.2 Pharmacokinetic properties

Pharmacokinetics:

When applied topically, diclofenac sodium, methyl salicylate and linseed oil are absorbed and penetrate into the subcutaneous tissue, muscle tissue and joint capsule.

5.3 Preclinical safety data

None Known

6. Pharmaceutical particulars

6.1 List of excipients

Carbomer-940	BP
Polyoxyl 40 Hydrogenated Castor Oil	USP
Disodium Edetate	BP
Benzyl alcohol	BP
Butylated Hydroxytoluene	BP
Propylene glycol	BP
Citric acid monohydrate	BP

Isopropyl alcohol	BP
Diethanolamine	BP
Purified water	BP

6.2 Incompatibilities
None Known

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store at a temperature below 30º C. Do not Freeze.

"KEEP OUT OF THE REACH OF CHILDREN".

6.5 Nature and contents of container
30 g printed laminated tube is pack in mono carton along with leaflet.
Such 12 tube is further packed in an outer carton.

6.6 Special precautions for disposal and other handling
No Special precautions for disposal and other handling.

7. Manufactured By
Scott-Edil Pharmacia Limited,
56, EPIP, Phase-I, Jharmajri,
Baddi, Distt. Solan- 173205 (H.P)
INDIA

8. Marketed By
FIRST J POCCO PHARM LTD.
89 DENIS OSADEBE WAY ASABA
DELTA STATE NIGERIA

9. Date of revision of the text
Not Applicable

10. DOSIMETRY (IF APPLICABLE)
Not applicable

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable