SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Product Name: **RELLXTRA GEL**

1. NAME OF THE MEDICINAL PRODUCT:

RELLXTRA GEL [Diclofenac Diethylamine BP 1.16%w/w, Linseed Oil BP 3.00%w/w, Menthol BP 5.00%w/w, Capsaicin USP .025%w/w]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Diclofenac Diethylamine BP	1.16%w/w
Eq. to Diclofenac Sodium BP	1.00%w/w
Linseed Oil BP	3.00%w/w
Menthol BP	5.00%w/w
Capsaicin USP	0.025%w/w
In aqueous gel base	q.s

3. Pharmaceutical form

Gel for topical administration

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
- localized 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

Adults: RELLXTRA 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.

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 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 warnings and precautions for use

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

RELLXTRA 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.

RELLXTRA GEL should not be co-administered with other products containing diclofenac. RELLXTRA 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.

RELLXTRA 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 other forms 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 RELLXTRA GEL but for a list of interactions known with oral diclofenac the data sheet for oral dosage forms should be consulted.

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/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 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-fetal 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 RELLXTRA 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, RELLXTRA 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 RELLXTRA 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.

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

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

4.9 Overdose

Signs and symptoms

The low systemic absorption of RELLXTRA GEL renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if RELLXTRA 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 Diclofenac gel 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)

RELLXTRA 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 RELLXTRA 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 RELLXTRA GEL. After topical administration of RELLXTRA GEL to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid. Maximum plasma concentrations of diclofenac are about 100 times lower than after oral administration of RELLXTRA GEL.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

Carbomer 940

Disodium Edetate

Triethanolamine

Sodium Methyl Paraben

Sodium Propyl Paraben

Propylene Glycol

Perfume

Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C in a dry & dark place. Do not Freeze.

Protect from light. Do not freeze.
KEEP ALL MEDICINES AWAY FROM CHILDREN

6.5 Nature and contents of container

The gel is filled into lamitube and packed in inner carton along with leaflet. Pack sizes available are 30g.

6.6 Special precautions for disposal and other handling

No special requirements.

7.0 Marketing Authorization Holder:

PATRICKLINGO

PHARMACEUTICAL LTD.

13, Obianwu Street,

Onitsha, Anambra State, Nigeria.

7.1 Manufacturer:

FANTASY DRUGS PVT. LTD
Plot No. C-66 -69, D-33 -36, Industrial Area, Hajipur, Vaishali,

Bihar-844 101, INDIA.

8.0 Marketing Authorization Numbers:

New Registration

9.0 Date of the First Authorization or Renewal:

Not Applicable

10.0 Date of Revision of the Text:

Not Applicable