Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

MOMENDOL 10% w/w GEL

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g contains 100 mg naproxen (10% w/w).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gel. Transparent, homogeneous and from colourless to slightly yellow and slightly sweet-smelling gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Momendol 10% gel is indicated in adults and children above 12 years for topical treatment of pain in musculoskeletal disorders such as myalgia, backache, stiff neck, bursitis, tendinitis, tenosynovitis, periarthritis, muscular sprains, contusions, hematoma.
Coadjuvant to orthopaedic and rehabilitation therapies.

4.2 Posology and method of administration

Posology

Spread Momendol Gel 10% on the painful area two times daily.
Maximum duration of use should not exceed 7 days.

Paediatric population

Momendol 10% gel is not recommended for use in children below 12 years.
The safety and efficacy of Momendol Gel 10% in children under 12 years have not yet been established.
No data are available.

Method of administration
Spread Momendol Gel 10% on the painful area and lightly massage to complete absorption.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Avoid using the gel on eyes, mucous membranes, wounds and/or skin lesions.

Blood concentrations reached by active substance absorbed through the skin are not such as to expose to risks of undesirable effects or make warnings concerning the systemic administration of the drug applicable.

However, use of Momendol Gel 10% is not recommended in patients presenting allergic reactions to acetylsalicylic

acid and/or other NSAIDs and is also not recommended in patients with history of allergic occurrences or allergic events in progress.

To prevent any phenomena of hypersensitivity or photosensitivity, avoid exposure to direct sunlight, including solarium, during the treatment and for 2 weeks afterwards.

The use of the product should be discontinued if the patients present any rash or irritation of the skin.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

The product is systemically little-absorbed and therefore, though possible, forms of interaction with other medicinal products are unlikely.

4.6 Fertility, pregnancy and lactation

The risk of harmful effects to be charged to the foetus and/or the child is not excluded. Therefore Momendol Gel 10% during pregnancy and/or breastfeeding should be used on medical advice and when strictly necessary. Momendol 10% gel is contraindicated during the third trimester of pregnancy.

4.7 Effects on ability to drive and use machines

Momendol Gel 10% has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are reported below according to the MedDRA classification and System Organ Class. The frequency of undesirable effect is defined as follows: Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000), Not known (cannot be estimated from the available data).

SOC/frequency	**Adverse reaction**
Skin and subcutaneous tissue disorders(1)	
Not known:	Erythema, Pruritus,Skin irritation, Skin burning sensation, Dermatitis contact, Bullous eruption, Photosensitivity reaction
Immune system disorders	
Not known:	Sensitisation(2)
General disorders and administration site conditions	
Not known:	Sensation of warmth

(1)With some non steroid anti-inflammatory dermal or trans-dermal products, derived from propionic acid, adverse skin reactions have been noted.(2)The prolonged use of products for topical administration may cause hypersensitivity phenomena. In such cases the treatment should be discontinued and a suitable alternative therapy instituted.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: topical drugs for treatment of joint and muscle pains – non-steroidal antiinflammatory drugs for topical use, ATC code: M02AA12.
NAPROXEN is a non-steroidal anti-inflammatory drug with analgesic and antiexudative properties.
Most of the pharmacological effects of naproxen, as with other NSAIDs, are mediated by inhibiting cyclo-oxygenase (COX) (a critical enzyme in the biosynthetic pathway of prostaglandins) with consequent suppression of prostaglandin biosynthesis. Naproxen inhibited COX-1 and COX-2 demonstrating equal selectivity for both isoform as indicated by COX-2/COX-1 IC50 ratio of 0.88.
The inhibited synthesis of prostaglandins accounts for the favourable effect on inflammation and pain.
Applied on the skin, naproxen proved effective in antiinflammatory activity tests in animals (carrageenan subplantaredema and exudative pleuricy test).

5.2 Pharmacokinetic properties

Following repeated doses of naproxen gel 10% administered topical, the peak systemic exposition is approx. 100-time lower compared to the maximum exposition observed after naproxen 200 mg administered oral.
In particular, the mean peak plasma concentration induced by Momendol gel 10% applied twice daily for 7 days was approx. equal to 0.5 μg/ml, and the mean area under the curve was equal to 5.4 μg/ml*h.

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, toxicity to reproduction and development.

For naproxen, the oral LD_{50} value ranges between 247 and 4520 mg/kg in rodents, whereas in dog is approximately equal to 1000 mg/kg. When administered topical, the bioavailability of naproxen is equal to 14% compared to oral dosing.
In vitro and in vivo tests confirmed the absence of genotoxicity. No carcinogenic potential have been detected.
Studies on reproductive functions showed that naproxen does not affect fertility nor exert teratogenic activity.

Like for other NSAIDs, delays in parturition were observed as well as normal postnatal development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol
Trolamine
Glycerol
Hydroxyethylcellulose

Sodium hydroxide
Perfume including menthol and eucalyptol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.
Store in the original package with lid closed in order to protect from light and evaporation.

6.5 Nature and contents of container

The product is packaged in aluminium tube, coated internally with epoxy-phenolic paint and provided with polypropylene closing top.
Tubes containing 50g or 100g.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F.S.p.A.
Viale Amelia 70
00181 Rome
Italy

8 MARKETING AUTHORISATION NUMBER

PA0959/002/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd April 2010

Date of last renewal: 30th December 2014

10 DATE OF REVISION OF THE TEXT

March 2015