

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### MOMENDOL 10% w/w GEL Naproxen

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What MOMENDOL GEL is and what it is used for
2. What you need to know before you take MOMENDOL GEL
3. How to take MOMENDOL GEL
4. Possible side effects
5. How to store MOMENDOL GEL
6. Contents of the pack and other information

### **1. WHAT MOMENDOL IS AND WHAT IT IS USED FOR**

MOMENDOL gel belongs to the class of non-steroidal analgesic-antiinflammatory drugs for topical use.

Momendol gel is used locally to treat muscular and articular pain such: muscle pain (myalgia), lumbar pain, stiff neck, inflammation of bursa near a joint or tendon (bursitis), inflammation of tendons (tendinitis), inflammation of synovia surrounding tendons (tenosynovitis), inflammation around a joint (periarthrits), strained muscles, contusions and hematoma.

Momendol may be used as an adjuvant in rehabilitation following trauma and/or orthopaedic surgery.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days of treatment

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOMENDOL GEL**

#### **Do not take MOMENDOL GEL**

- If you are allergic to Naproxen or any of the other ingredients of this medicine (listed in section 6). In third trimester of pregnancy (see “Pregnancy and breast-feeding”).

#### **Warning and precautions**

Talk to your doctor or pharmacist before taking Momendol gel:

- If you have allergic diseases such as asthma, urticaria, rhinitis, nasal polyps, angioedema and anaphylactic reactions after the intake of medicines containing acetylsalicylic acid and/or non-steroidal anti-inflammatory drugs
- If you are taking other medicines requiring caution, see next section “Other medicines and MOMENDOL GEL”.

The product must not be applied on eyes, mucous membranes, wounds and/or skin lesions

- In order to avoid any events of hypersensitivity or photosensitivity, avoid exposure to direct sunlight, including solarium, tanning beds or lamps , during the treatment and for two weeks afterwards (see also “Possible Side Effects” paragraph).
- The use of the product should be discontinued if the patients present any rash or irritation of the skin.

#### **Other medicines and MOMENDOL GEL**

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines.

#### **MOMENDOL with food, drink and alcohol**

No influence.

#### **Pregnancy and breast-feeding**

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Driving and using machines**

Momendol gel has no influence on the ability to drive and use machines.

### **3. HOW TO TAKE MOMENDOL GEL**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Spread Momendol gel on the painful area two times daily and lightly massage to complete absorption.

Momendol 10% gel is not recommended for use in children below 12 years due to the lack of data on safety and efficacy in children.

Do not use for more than 7 days. Do not exceed the recommended doses.

If pain persists or worsens, consult your doctor or pharmacist.

#### **If you take more Momendol gel than you should**

No overdose cases have been reported.

If you used the medicinal more times than is recommended or in case of accidental ingestion of the medicinal, contact your doctor or pharmacist.

If you have any further question on the use of this product, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, MOMENDOL GEL can cause side effects, although not everybody gets them.

Not known (frequency cannot be estimated from the available data)

- Redness of the skin (Erythema)
- Itching (Pruritus)
- Skin irritation

- Heat or burning sensation
- Rash over the area in which the gel was applied (Dermatitis contact)
- Fluid-filled blisters (Bullous eruption)
- Photosensitivity reactions
- Hypersensitivity reactions
- Application site warmth

The prolonged use of products for topical administration may cause hypersensitivity phenomena. In that case, discontinue the treatment, see your doctor and report what happened to him.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 (Tel: +353 1 6764971; Fax: +353 1 6762517) - Website: [www.hpra.ie](http://www.hpra.ie) - e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE MOMENDOL GEL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and on the box. The expiry date refers to the last day of that month.

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.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines no longer use. These measures will help to protect the environment.

## 6. CONTENT OF THE PACK AND OTHER INFORMATION

### What MOMENDOL GEL contains

The active substance is naproxen at the 10% w/w concentration (1 g of product contains naproxen 100 mg).

The excipients are: isopropyl alcohol, trolamine, glycerol, hydroxyethylcellulose, sodium hydroxide, perfume including menthol and eucalyptol, purified water.

### What MOMENDOL GEL looks like and contents of the pack

MOMENDOL comes in the form of a transparent, homogeneous, colourless to slightly yellow, sweet-smelling gel.

Each package contains a 50 g or 100 g tube of gel

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

### Manufacturer

Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.p.A.

Via Vecchia del Pinocchio, 22  
60131 Ancona  
Italy  
Tel 0039 071 8091  
Fax 0039 071 809440

**This medicinal product is authorised in the Member States of the EEA under the following names:**

[To be completed nationally]

**This leaflet was last approved in:**

[To be completed nationally]