

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Movelat Muscle Pain Relief Gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mucopolysaccharide polysulfate (MPS) 0.2% w/w

Salicylic acid 2.0% w/w

### Excipient(s) with known effect

Rosemary Oil (containing citral, eugenol, geraniol, linalool, citronellol and limonene) 0.06% w/w

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Topical Gel.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Movelat Muscle Pain Relief Gel is a mild to moderate anti-inflammatory and analgesic topical preparation for the symptomatic relief of muscular pain and stiffness, sprains and strains.

### 4.2 Posology and method of administration

#### **Adults, the elderly and children over 12 years of age:**

Movelat Muscle Pain Relief Gel should be massaged to the affected area up to four times daily. Depending on the size of the affected site to be treated two to six inches (5-15 cm, equivalent to roughly 2-6g) should be applied, at approximately 4 hourly intervals.

It is recommended that the treatment be reviewed after 7 days if symptoms worsen or do not improve.

**Children:**

The use of Movelat Muscle Pain Relief Gel is contra-indicated in children under 12 years of age.

**4.3 Contraindications**

Keep away from the eyes. Not to be used on large areas of skin, broken or sensitive skin, infected skin, eczema or on mucous membranes.

Not to be used on children under 12 years of age.

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Hypersensitivity to aspirin or other non-steroidal anti-inflammatory drugs (including when taken by mouth) especially where associated with a history of asthma.

Not to be used on the breast area during lactation (see section 4.6).

**4.4 Special warnings and precautions for use**

For external use only. The stated dose should not be exceeded. If the condition persists or worsens, consult a doctor or pharmacist. Although systemic absorption of topical salicylate is much less than for oral dosage forms, the side effects of salicylates are theoretically possible.

Consult a doctor or pharmacist before use if pregnant, breast-feeding, asthmatic have pre-existing renal damage or on any prescribed medicines.

Some people may experience discomfort, particularly those with sensitive skin or if used in hot weather or after a bath. Wash hands immediately after use.

Discontinue use if excessive irritation or other unwanted effects occur.

Instruct patients not to smoke or go near naked flames – risk of severe burns.

Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

**Ingredients with specified warnings**

This medicine contains fragrance (rosemary oil) with citral, eugenol, geraniol, linalool, citronellol and limonene which may cause allergic reactions.

**4.5 Interaction with other medicinal products and other forms of interaction**

Although no adequately controlled interaction studies have been undertaken, it is possible that excessive use of topical salicylates may increase the effect of coumarin anticoagulants. It is therefore advisable that caution be exercised with patients who are taking coumarin anticoagulants.

Salicylic acid may increase skin permeability for other topically applied medications (see section 5.1).

#### **4.6 Fertility, Pregnancy and lactation**

As with most medicines, patients must seek the doctor's or pharmacist's advice before using if they are pregnant or breast feeding.

##### Pregnancy

Do not use during the first trimester or during late pregnancy.

##### Breastfeeding

Not to be used on the breast area during lactation.

#### **4.7 Effects on ability to drive and use machines**

None.

#### **4.8 Undesirable effects**

In this section, frequencies of undesirable effects are defined as follows: Very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $< 1/10,000$ ).

##### *Skin and subcutaneous tissue disorders*

Uncommon: Local skin reactions/irritations (e.g. redness, burning sensation or rashes).

##### 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 the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

#### **4.9 Overdose**

Overdose associated with localised/topical application is unlikely.

Following accidental ingestion of Movelat Muscle Pain Relief Gel, individuals may present with the symptoms of salicylate poisoning (hyperventilation, tinnitus, deafness, vasodilation, sweating). The stomach should be emptied and plasma salicylate, plasma pH and electrolytes should be monitored. Forced alkaline diuresis

may be required if the plasma salicylate levels are in excess of 500 mg/litre (3.6 mmol/litre) in adults or 300 mg/litre (2.2 mmol/litre) in children.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: topical agent used in the treatment of myalgia and arthralgia.

ATC code: M02AC (Topical Products for Joint and Muscular Pain – Preparations with salicylic acid derivatives).

Mucopolysaccharide polysulphate is a non-steroidal drug recognised as having:

- Anti-inflammatory activity: through a weak inhibitory effect of PGE<sub>2</sub> synthesis and an indirect effect on LTB<sub>4</sub> production based on *in vitro* studies.
- Anti-coagulant activity: as a heparinoid.
- Thrombolytic activity: through potentiation of urokinase activity.
- Anti-exudatory activity: through inhibition of hyaluronidase.

Salicylic acid, a non-steroidal anti-inflammatory drug, is employed in the formulation for its keratolytic activity; and also has anti-inflammatory and analgesic properties.

Due to the route of administration and topical nature of the product, the effects of mucopolysaccharide and salicylic acid are topical/localised only.

### 5.2 Pharmacokinetic properties

Radiochemical studies of absorption following cutaneous application of mucopolysaccharide polysulphate have shown that between 0.3 and 4% of the mucopolysaccharide administered is absorbed by tissues other than at the site of application within the first eight hours. Typically between 1.7% and 4.6% will be absorbed within two to four days. Animal studies have also shown that mucopolysaccharide is bound intracellularly within the subcutis. Peak serum concentrations following cutaneous application are below the threshold of physiological relevance for coagulation.

Mucopolysaccharide is excreted in the urine partly unchanged and partly as depolymerized, shorter chain length molecules.

The plasma level of salicylic acid following cutaneous application of Movelat Muscle Pain Relief Gel has been shown to remain constant at approximately 0.2 µg/ml even after repeated dosing. The total excretion of salicylate reaches a constant figure of approximately 12 mg/day. Over a seven-day period, approximately 6.9% of the administered dose is excreted renally, primarily as salicylic acid.

### **5.3 Preclinical safety data**

None stated

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Isopropyl alcohol

Monoethanolamine

Carbomer (Carbopol 940)

Disodium edetate (Titriplex III)

Polyethylene glyceryl-oleate (Tagat O)

Rosemary oil (containing citral, eugenol, geraniol, linalool, citronellol and limonene)

Purified water

### **6.2 Incompatibilities**

None.

### **6.3 Shelf life**

5 years.

### **6.4 Special precautions for storage**

Store below 25°C.

### **6.5 Nature and contents of container**

Lacquered aluminium tubes.

Pack sizes: 14, 30, 50, 100g

### **6.6 Special precautions for disposal**

Not applicable.

**7      MARKETING AUTHORISATION HOLDER**

Thornton & Ross Ltd.  
Linthwaite  
Huddersfield  
HD7 5QH  
UK

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 00240/0555

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05/12/2017

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