

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

**MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007**

**(S.I. No.540 of 2007)**

**PA0540/118/001**

Case No: 2066252

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**sanofi-aventis Ireland Limited**

**Citywest Business Campus, Dublin 24, Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Orugesic 2.5% w/w Gel**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **31/07/2009** until **11/10/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Orugesic 2.5% w/w Gel

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoprofen 2.5 % w/w.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Cutaneous Gel

A clear, colourless or practically colourless, transparent gel.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

In the topical management of soft tissue trauma and for the relief of pain and inflammation associated with extra-articular rheumatism and osteoarthritis in joints.

##### 4.2 Posology and method of administration

Orugesic Gel is for cutaneous use.

###### Recommended Dosage

Adults: Application by gentle massage 2 to 4 times daily. Treatment should not extend beyond 6 weeks.

Elderly: There are not specific dosage recommendations for the elderly. The lowest dose compatible with adequate safe clinical controls should be employed in the elderly, who are more prone to adverse events.

Children: Not recommended for children under 12 years of age.

Contact with the eyes or mucosa should be avoided.

##### 4.3 Contraindications

- Patients with a history of hypersensitivity reactions (e.g. bronchospasm, rhinitis, urticaria) in response to ketoprofen, aspirin or non-steroidal anti-inflammatory drugs.
- Hypersensitivity to any of the excipients of Orugesic Gel.
- Use on pathological skin changes such as eczema or acne; or in infectious skin or open wounds.
- Patients with active peptic ulceration.
- Use with occlusive dressings.
- Simultaneous use to the same site with any other topical cream.
- Use in children under 12 years of age.
- Third trimester of pregnancy.

## 4.4 Special warnings and precautions for use

1. Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. The total dose of product should not exceed 15 g daily.
2. If there is no improvement, or the condition is aggravated, the doctor should be consulted.
3. Although systemic effects should be low, the gel should be used with caution in patients with renal, cardiac or hepatic impairment, history of peptic ulceration or inflammatory bowel disease, intracranial haemorrhage or bleeding diathesis. Isolated cases of systemic adverse reactions, consisting of renal affection, have been reported.
4. Elderly Patients – Non steroidal anti-inflammatory drugs (NSAIDs) should be used with particular caution in elderly patients who are more prone to adverse events. The lowest dose compatible with adequate safe clinical control should be employed. See also Section 4.2.
5. The gel must not be used with occlusive dressings.
6. The gel must not come into contact with mucous membranes of the eyes.
7. The treatment should be interrupted if a rash appears.
8. Direct sunlight, including solarium, should be avoided during treatment and for 2 weeks following treatment.
9. The tube should be closed after use.
8. Hand washing is recommended after application.

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

Interactions are unlikely as serum concentrations following topical administration are low.

Serious interactions have been recorded after the use of high dose methotrexate with non-steroidal anti-inflammatory agents, including ketoprofen, when administered by the systemic route.

## 4.6 Pregnancy and lactation

As the safety of ketoprofen in pregnant women has not been evaluated, the use of ketoprofen during the first and second trimester of pregnancy should be avoided.

During the third trimester of pregnancy, all prostaglandin synthetase inhibitors including ketoprofen may induce cardiopulmonary and renal toxicity in the foetus.

At the end of the pregnancy, prolonged bleeding time in both mother and child, may occur.

Ketoprofen is not recommended in nursing mothers.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

Localised skin reactions have been reported which may secondarily spread outside the application site. Erythema, pruritus and photosensitivity reactions have been reported.

Uncommon (1/100-1/1000)

Skin: Erythema, itch, pruritus, eczema.

Rare (<1/1000)

Skin: Photosensitivity reactions, bullous eruptions, urticaria.

Very rare (<1/10000)

Cases of aggravation of previous renal insufficiency have been reported.

## 4.9 Overdose

Overdose is unlikely to be caused by topical administration. If accidentally ingested, the gel may cause systemic adverse effects depending on the amount ingested. However, if this occurs, treatment should be supportive and symptomatic in accordance with the overdosage of oral antiphlogistics.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Ketoprofen is a non-steroidal anti-inflammatory drug. It has anti-inflammatory and analgesic actions.

### 5.2 Pharmacokinetic properties

A non-steroidal anti-inflammatory drug of the phenylpropionic acid group readily absorbed from the gastrointestinal tract, strongly protein bound and excreted mainly in the urine after glucuronidation.

Applied locally as a gel, ketoprofen is absorbed very slowly and there is no accumulation in the body. The bioavailability of the gel relative to oral forms of ketoprofen is around 5%. The low systemic bioavailability suggests that systemic effects are unlikely.

### 5.3 Preclinical safety data

Not relevant.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbomer 980  
Triethanolamine  
Lavender oil  
Ethanol 96 %  
Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

3 years.

### 6.4 Special precautions for storage

Do not store above 25°C. Keep away from naked flames.

### 6.5 Nature and contents of container

Aluminium tube internally lacquered with polycondensed epoxyphenol varnish, with the tip sealed by the same material. The cap is a moulded white polypropylene screw cap.

The tube is supplied in an outer cardboard carton.

Pack sizes: 10g, 15g, 20g - sample packs,  
40g, 45g, 50g, 60g, 75g, 100g, 150g.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Sanofi-Aventis Ireland Ltd.  
Citywest Business Campus  
Dublin 24

## **8 MARKETING AUTHORISATION NUMBER**

PA 540/118/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 12 October 1994

Date of last renewal: 12 October 2004

## **10 DATE OF REVISION OF THE TEXT**

July 2009