Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oruvail 2.5 % w/w Gel.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The gel contains 2.5% w/w of ketoprofen.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
A clear, colourless or practically colourless, transparent gel free from visible lumps.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

The route of administration is topical to the affected area.

Recommended Dosage:

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

Elderly: There are no specific dosage recommendations for the elderly. 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 section 4.4, Special warnings and precautions for use*).

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 Oruvail 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

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. The total dose of product should not exceed 15g daily. Patients treated with NSAIDs long- term should undergo regular medical supervision to monitor for adverse events.

If there is no improvement, or the condition is aggravated, the doctor should be consulted.

Although systemic effects with Oruvail Gel should be low, care should be taken in the following groups of patients:

In patients with renal, cardiac or hepatic impairment, caution is required since the use of NSAIDs may result in deterioration of renal function. Assessment of renal function should occur prior to the initiation of therapy and regularly thereafter. Isolated cases of systemic adverse reactions consisting of renal affection have been reported.

Elderly Patients are particularly susceptible to the adverse events of NSAIDs. Prolonged use of NSAIDs in the elderly is not recommended. Where prolonged therapy is required, patients should be reviewed regularly.

The gel must not be used with occlusive dressings.

The gel must not come into contact with mucous membranes of the eyes.

Ketoprofen should be used with caution in patients with a history of peptic ulceration or inflammatory bowel disease.

As NSAIDs can interfere with platelet function, they should be used with caution in patients with intracranial haemorrhage and bleeding diathesis.

The treatment should be interrupted if a rash appears.

Direct sunlight, including solarium, should be avoided during treatment and for 2 weeks following treatment.

The tube should be closed after use.

Hand washing is recommended after application.

4.5 Interaction with other medicinal products and other forms of interaction

It is considered unsafe to take NSAIDs in combination with warfarin or heparin unless under direct medical supervision.

Although interactions are unlikely as serum concentrations following cutaneous administration are low, care should be taken in patients treated with any of the following drugs as interactions have been reported (with systemic forms):

Anti-hypertensives: reduced anti-hypertensive effect.

Diuretics: reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

Lithium: decreased elimination of lithium.

Methotrexate: decreased elimination of methotrexate.

Cyclosporin: increased risk of neprotoxicity with NSAIDs.

Other NSAIDs: avoid concomitant use of two or more NSAIDs.

Corticosteroids: increased risk of gastrointestinal bleeding.

Aminoglycosides: reduction in renal function in susceptible individuals, decreased elimination of aminoglycoside and increased plasma concentrations.

Probenecid: reduction in metabolism and elimination of NSAID and metabolites.

Oral hypoglycemic agents: inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increased risk of hypoglycaemia.

4.6 Fertility, pregnancy and lactation

As the safety of ketoprofen is 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 ketaprofen 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 antiphlogisitics.

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 bioavaiabilty suggest that systemic effects are unlikely.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Ethanol 96% v/v
Trolamine
Lavender oil
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 the tube away from naked flames.

6.5 Nature and contents of container

Aluminium tube internally lacquered with polycondensed epoxyphenol resin, with the tip sealed by the same material. The cap is a moulded white polyproplene screw cap. The tube is supplied in an outer cardboard carton.

Pack sizes: 15g, 25g, 30g, 45g, 50g, 60g, 100g and 150g tubes.

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 0540/119/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 August 1991

Date of last renewal: 12 August 2006

10 DATE OF REVISION OF THE TEXT

January 2011