Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Feldene Topigel 5mg/g Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains 5mg piroxicam.

Excipients: Propylene glycol 200mg/g

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gel
Clear, pale-yellow gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For local symptomatic relief of pain and inflammation in the trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism.

4.2 Posology and method of administration

Feldene Topigel is for external use only. Apply 1g of the gel, corresponding to 3cms, (approximately 1 1/4 inches) and rub into the affected site three to four times daily leaving no residual material on the skin. Occlusive dressings should not be used.

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 4.4*

In the absence of experience, Feldene Topigel should not be used in children.

4.3 Contraindications

Feldene Topigel should not be used in patients who have previously shown a hypersensitivity to the gel or piroxicam in any of its forms. The potential exists for cross sensitivity to aspirin and other non-steroidal anti-inflammatory agents.

Patients with active peptic ulceration.

Patients with a history of hypersensitivity reactions (e.g. bronchospasm, rhinitis, urticaria) in response to Feldene Topigel, aspirin or non-steroidal anti-inflammatory drugs.

Feldene Topigel should not be given to patients in whom aspirin and other non-steroidal anti-inflammatory agents induce the symptoms of asthma, rhinitis, angioedema or urticaria.

Use in areas affected by open lesions, dermatoses or infection.

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 recommended maximum period of treatment is 7 days. Patients treated with NSAIDs longterm should undergo regular medical supervision to monitor for adverse events.

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.

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

Feldene Topigel 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.

Piroxicam should be only used with caution in patients with a history of or existent peptic ulceration, intestinal inflammatory disease or those with renal dysfunction or hepatic disease. The elderly require particular care because of their vulnerability to gastro-intestinal bleeding.

Patients on prolonged therapy with piroxicam should be kept under regular surveillance.

Piroxicam may prolong bleeding time and decrease platelet aggregation

If local irritation or aggravation of the condition occurs, use of the gel should be discontinued and appropriate therapy instituted as necessary.

Keep away from the eyes or mucosa.

4.5 Interaction with other medicinal products and other forms of interaction

Care should be taken in patients treated with any of the following drugs as interactions have been reported:

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

Piroxicam is highly protein-bound. There is therefore a possibility of interaction with such drugs as coumarin type anticoagulants. In addition, some quantitative variation in handling of oral Feldene has been noted when aspirin is used concurrently. Although in mind when designing concurrent therapy, it is unlikely that significant interactions will occur with Feldene Topigel.

4.6 Pregnancy and lactation

Use in pregnancy: Although no teratogenic effects were seen when piroxicam was orally administered in animal testing, the safety of the gel during pregnancy or during lactation has not yet been established. Piroxicam inhibits prostaglandin synthesis and release through a reversible inhibition of the cyclo-oxygenase enzyme.

This effect, as with other non-steroidal anti-inflammatory agents, has been associated with an increased incidence of dystocia and delayed parturition in pregnant animals when drug administration was continued into late pregnancy. Non-steroidal anti-inflammatory agents are also known to induce closure of the ductus arteriosus in infants.

Nursing mothers: A preliminary study indicates that following oral administration piroxicam is found in maternal milk in a concentration of approximately 1% of that reached in plasma. Feldene Topigel is not recommended for use in nursing mothers as clinical safety has not been established.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Treatment-related adverse effects have been reported only rarely.

In clinical piroxicam studies, adverse effect occurred in only 2.6% of study subjects

Organ System	**Frequency**	**Adverse Effect**
Skin and subcutaneous tissue	Common (≥1/100, < 1/10)	Pityroid desquamation; erythema; skin rash; local skin irritation; pruritus; reactions at the sites of application.
	Rare (≥ 1/10,000, < 1/1000)	Contact dermatitis; eczema; photosensitivity reaction; skin discoloration and staining of clothes when gel is not rubbed in completely.

If the gel causes local skin irritation, its use should be stopped and it should be replaced with some other treatment, if needed.

4.9 Overdose

Since Feldene Topigel is a topical application the possibility of overdosage is very remote.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory preparations, non-steroids for topical use
ATC code: M02AA07

Piroxicam is a non-steroidal anti-inflammatory agent useful in the treatment of inflammatory conditions. Although the mode of action for this agent is not precisely understood, piroxicam inhibits prostaglandin synthesis and release through a reversible inhibition of the cyclo-oxygenase enzyme.

5.2 Pharmacokinetic properties

On the basis of various pharmacokinetic and tissue distribution studies in animals, with piroxicam gel 0.5%, the highest concentrations of piroxicam were achieved in the tissues below the site of application with low concentrations being reached in the plasma. Piroxicam gel 0.5% was continuously and gradually released from the skin to underlying tissues, equilibrium between skin, and muscle or synovial fluid appeared to be reached rapidly, within a few hours of application.

From a pharmacokinetic study in man, 2g of the Gel was applied to the shoulders of normal volunteers twice daily (corresponding to 20mg piroxicam/day) for 14 days, plasma levels of piroxicam rose slowly, reaching steady state after about 11 days. The plasma levels at this time were between 300-400 ng/ml, or one-twentieth of those observed in subjects receiving 20mg orally.

The serum half-life of piroxicam is approximately 50 hours.

5.3 Preclinical safety data

Not known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Carbomer 980
Ethanol
Benzyl alcohol
Di-isopropanolamine
Hyetellose
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Aluminium, blind-ended tube incorporating epoxy-phenol internal lacquer with a white, vinyl, pressure-sensitive polyethylene end seal, fitted with a polypropylene cap containing 30g Feldene Topigel.

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

Pfizer Healthcare Ireland,
9 Riverwalk,
National Digital Park,
Citywest Business Campus,
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 0822/022/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 January 1991

Date of last renewal: 29 January 2006

10 DATE OF REVISION OF THE TEXT

August 2008