SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Feldene 0.5% w/w Gel.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 5 mg piroxicam (0.5% w/w).

Excipient with known effect:
Feldene Gel contains 200 mg/g propylene glycol, 10 mg/g benzyl alcohol and 240 mg/g anhydrous ethanol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Feldene Gel is a non-steroidal anti-inflammatory agent indicated for a variety of conditions characterised by pain and inflammation, or stiffness. It is effective in the treatment of osteoarthritis of superficial joints such as the knee, acute musculoskeletal injuries, periarthritis, epicondylitis, tendinitis and tenosynovitis.

4.2 Posology and method of administration

Posology

Adults
No occlusive dressings should be employed. Apply 1 g of Gel, corresponding to 3cm, and rub into the affected site three to four times daily leaving no residual material on the skin. Therapy should be reviewed after 4 weeks.

Paediatric population

Dosage recommendations and indications for the use of Feldene Gel in children have not been established.

Elderly
No special precautions are required.

Method of administration

Feldene Gel is for external use only.

4.3 Contraindications

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

The potential exists for cross sensitivity to aspirin and other non-steroidal anti-inflammatory agents (NSAIDs). Feldene Gel should not be given to patients in whom aspirin and other non-steroidal anti-inflammatory agents induce the symptoms of asthma, nasal polyps, angioneurotic oedema or urticaria.

4.4 Special warnings and precautions for use

Life-threatening cutaneous reactions, including drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the use of systemic administration of piroxicam. These reactions have not been associated with topical piroxicam, but the possibility of occurring with topical piroxicam cannot be ruled out.

Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of SJS or TEN is within the first week of treatment.

If signs or symptoms of SJS or TEN (e.g. progressive skin rash often with blisters or mucosal lesions) are present, piroxicam treatment should be discontinued.

The best results in managing SJS and TEN come from early diagnosis and immediate discontinuation of any suspect drug. Early withdrawal is associated with a better prognosis.

If the patient has developed SJS or TEN with the use of piroxicam, piroxicam must not be re-started in this patient at any time.

Keep away from the eyes and mucosal surfaces. Do not apply to any sites affected by open skin lesions, dermatoses or infection.

NSAIDs, including piroxicam, may cause interstitial nephritis, nephrotic syndrome and renal failure. There have also been reports of interstitial nephritis, nephrotic syndrome and renal failure with topical piroxicam, although the causal relationship to treatment with topical piroxicam has not been established. As a result, the possibility that these events may be related to the use of topical piroxicam cannot be ruled out.

This medicinal product contains propylene glycol and may cause skin irritation. If local irritation develops, the use of the Feldene Gel should be discontinued and appropriate therapy instituted as necessary. Because this medicine contains propylene glycol, Feldene Gel should not be used on open wounds or large areas of broken or damaged skin (such as burns).

This medicinal product contains benzyl alcohol which may cause mild local irritation.

Benzyl alcohol may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Fertility
Based on the mechanism of action, the use of NSAIDs, including piroxicam may delay or prevent rupture of ovarian follicles, which has been associated with reversible infertility in some women. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of NSAIDs, including topical piroxicam should be considered.

Pregnancy
There are no studies of the use of topical piroxicam in pregnant women. Studies in animals have shown reproductive toxicity with the systemic formulations (see section 5.3), but their relevance to the use of topical formulations in pregnant women is unknown. As a precautionary measure, it is preferable to avoid the use of topical piroxicam in pregnant women.

Inhibition of prostaglandin synthesis might adversely affect pregnancy. Data from epidemiological studies suggest an increased risk of spontaneous abortion after the use of prostaglandin synthesis inhibitors in early pregnancy. In animals, administration of prostaglandin synthesis inhibitors has been shown to result in increased pre- and post-implantation loss. Therefore, the use of Feldene Gel during pregnancy is not recommended.

Breast-feeding
Feldene Gel 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

Not relevant.

4.8 Undesirable effects

Feldene Gel is well tolerated. Mild to moderate local irritation, erythema, pruritus and dermatitis may occur at the application site. The systemic absorption of Feldene Gel is very low. In common with other topical non-steroidal anti-inflammatory agents, systemic reactions occur infrequently and have included minor gastro-intestinal side-effects such as nausea and dyspepsia. Cases of abdominal pain and gastritis have been reported rarely. There have been isolated reports of bronchospasm and dyspnoea (see also section 4.3).

Severe cutaneous adverse reactions (SCARs): Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported very rarely (see section 4.4).

Contact dermatitis, eczema and photosensitivity skin reaction have also been observed from post-marketing experience.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdosage is unlikely to occur with this topical preparation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 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. New data are presented on the anti-inflammatory and analgesic effects of Feldene Gel compared with its vehicle and indometacin 1% Gel in rats and guinea pigs. Using established animal models of pain and inflammation, Feldene Gel was as effective as oral Feldene and indometacin 1% Gel and significantly more effective than its vehicle.

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 20 mg 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 20 mg orally.

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

5.3 Preclinical safety data

In reproductive toxicity studies, piroxicam increases the incidence of dystocia and delayed parturition in animals, when drug administration is continued during pregnancy. Administration of prostaglandin synthesis inhibitors has also been shown to result in increased pre-and post-implantation loss. These observations were made using parenteral dosing, and as noted in section 5.2, equilibrium plasma levels of piroxicam obtained in patients using the topical gel are only approximately 5% of those achieved using an equivalent dose of parenteral product. In animal studies with the topical gel, there were no treatment-related

adverse effects using 1 gram of gel daily for up to 30 days, nor was there evidence of photo-allergy or skin sensitisation.

6.1 List of excipients

Propylene Glycol (E1520)
Carbopol 980
Ethanol
Benzyl Alcohol (E1519)
Di-isopropanolamine
Hydroxyethyl Cellulose
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30^0C.

6.5 Nature and contents of container

Aluminium blind-ended tube incorporating epoxy-phenol internal lacquer with a polymer end seal, fitted with a polypropylene cap containing either 60 g or 112 g of Feldene Gel.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT 13 9NJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00057/0284

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/04/1989 / 20/03/2009

10 DATE OF REVISION OF THE TEXT

15/07/2021