PFIZER
FELDENE* GEL 0.5%
Piroxicam

1. NAME OF MEDICINAL PRODUCT

FELDENE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3. PHARMACEUTICAL FORM

Gel: 0.5% (5 mg per gram of gel) by weight anhydrous piroxicam.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indications for Use:
In the topical management of pain, inflammation or stiffness associated with osteoarthritis, acute musculoskeletal disorders such as bursitis, periarthritis, tendonitis, post-traumatic conditions, sprains and lower back pain.

4.2 Posology and method of administration

Posology
Adults: Apply 1 g of the gel, (approximately 3 cm or 1 1/4 inches) to the affected area twice to four times daily.

In the elderly, who are more prone to adverse events, the lowest dose compatible with adequate safe clinical control should be employed.

Occlusive dressings should not be used.

Treatment should be reviewed at regular intervals and discontinued if no benefit is seen or if intolerance occurs.

Method of administration
Feldene Gel is for external use only.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Paediatric population
Use in children in the absence of experience.

Use in patients whom asthma, rhinitis or urticaria are induced by aspirin or other non-steroidal anti-inflammatory agents (NSAIDs).

Use on areas with open skin 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. Patients treated with NSAIDs long term should undergo regular medical supervision to monitor for adverse events.

Piroxicam should be used with care 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 gastrointestinal bleeding.

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

Piroxicam may prolong bleeding time and decrease platelet aggregation.

Skin Reactions

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.

Cases of fixed drug eruption (FDE) have been reported with piroxicam. Piroxicam should not be reintroduced in patients with history of piroxicam-related FDE. Potential cross reactivity might occur with other oxicams.

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 or aggravation of the condition occurs, stop medication. 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

Piroxicam is highly protein-bound. There is therefore a possibility of interaction with such drugs as coumarin anticoagulants. In addition, some quantitative variation in handling of the drug has been noted when aspirin is used concurrently. Although no clinically significant interactions have been demonstrated, these points should be kept in mind when designing concurrent therapy. It is unlikely that significant interactions will occur with topical use.

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
The safety of topical piroxicam use during pregnancy has not yet been established.

There are no studies of the use of topical piroxicam in pregnant women. Studies in animals have shown reproductive toxicity with 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.

Animal testing did not show a teratogenic effect with oral piroxicam although a delay in parturition occurred as with other agents of this group.

Breast-feeding
Oral administration results in excretion in breast milk at a concentration of 1% that in

plasma. This product 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

Side effects include local irritation, rash, possibly photosensitivity.

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

Fixed drug eruption (see section 4.4) at an unknown frequency.

In post-marketing experience, the following additional dermatological effects have been reported: contact dermatitis, eczema and photosensitivity skin reactions.

Mild but transient skin discoloration and staining of clothing have been noted when the gel is not rubbed in completely.

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.

4.9 Overdose

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

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.

5.2 Pharmacokinetic properties

A non-steroidal anti-inflammatory analgesic absorbed significantly through skin but giving high local concentrations and low serum levels. Systemic kinetics are similar to those after oral dosing. The serum half-life of piroxicam is approximately 50 hours.

5.3 Preclinical safety data

Subacute and chronic toxicity studies have been carried out in rats, mice, dogs, and monkeys, using parenteral doses which ranged from 0.3 mg/kg/day to 25 mg/kg/day. Non-clinical data show effects typical of a non cox-selective NSAID; namely, renal papillary necrosis and gastrointestinal lesions. With regard to the latter, the monkey proved to be quite resistant to this effect and the dog unusually sensitive. 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 and defects in foetal bone mineralisation. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Special precautions for storage

Refer to the outer carton for storage condition.

6.3 Nature and content of container

15 g/tube
25 g/tube
Not all pack sizes may be marketed.

6.4 Instructions for use and handling

For external use only. Keep out of reach of children.

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April 2021
Hong Kong