APPLICANT	:	ADCOCK INGRAM LIMITED	
PROPRIETARY NAME	:	FASTUM® GEL	
(DOSAGE FORM)		(Gel)	
STRENGTH	:	Ketoprofen 2,5 g per 100 g	MODULE 1
REGISTRATION NUMBER	:	Z/3.1/165	1.3.1.1

1.3.1.1 PACKAGE INSERT

SCHEDULING STATUS: **S1**

PROPRIETARY NAME: FASTUM® GEL

(AND DOSAGE FORM) (GEL)

COMPOSITION:

Each 100 g contains:

Ketoprofen 2,5 g (i.e. 2,5 % m/m)

List of excipients: Carbomer 940, ethanol (96%), neroli essence, lavender essence, purified water and triethanolamine.

PHARMACOLOGICAL CLASSIFICATION:

A 3.1 Antirheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION:

Ketoprofen is a non-steroidal anti-inflammatory agent.

Since ketoprofen is an inhibitor of prostaglandin synthesis it provides for anti-inflammatory, analgesic effects. **FASTUM GEL** is ketoprofen in an excipient suitable for allowing it to reach the site of inflammation by transcutaneous route, providing the local treatment of painful joints, tendons, ligaments and muscles.

INDICATIONS:

For the relief of localised pain and inflammation associated with acute musculo-skeletal injuries.

CONTRAINDICATIONS:

Known hypersensitivity to any of the ingredients or to other substances that are closely related to ketoprofen from a chemical point of view (or other non-steroidal anti-inflammatory drugs as well as acetylsalicylic acid and its derivatives).

Safety in children has not been established.

WARNINGS:

The prolonged use of **FASTUM GEL** may cause hypersensitivity phenomena. In such cases the treatment should be discontinued and a suitable alternate therapy instituted. Since the application of **FASTUM GEL** may provoke photosensitisation, the treated skin area should not be exposed to the sun both during treatment and for two weeks thereafter.

INTERACTIONS:

FASTUM GEL should be used with caution in patients who are receiving coumarin anticoagulants.

PREGNANCY AND LACTATION:

Safety of **FASTUM GEL** during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Treatment should not exceed 7 days.

Persons 12 years and older: Apply to the affected area once or twice daily by gently massaging in order to help absorption. Apply 5 to 15 cm of gel with each application (100 to 300 mg ketoprofen).

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Considering the very low systemic absorption by topical application, systemic side effects are not expected, but cannot be excluded.

Side effects experienced with systemically absorbed ketoprofen include:

The following convention is used to define the frequency of side effects: Very common (>1/10); Common (>1/100, <1/10); Uncommon (>1/1 000, <1/100); Rare (>1/10 000, <1/1 000): Very rare (<1/10 000) including isolated reports.

Gastrointestinal disorders

Rare: gastrointestinal, peptic ulceration and gastrointestinal bleeding.

Nervous system disorders

Rare: headache.

Less frequent: dizziness, nervousness, depression, insomnia and drowsiness.

Ear and labyrinth disorders

Less frequent: tinnitus.

Immune system disorders

Rare: sensitivity reactions.

Skin and subcutaneous tissue disorders

The following side effects have been reported and the frequencies are unknown: Skin rashes and pruritus.

General disorders and administration site conditions

The following side effect has been reported and the frequency is unknown: oedema.

Eye disorders

Less frequent: blurred vision

Rare: other ocular reactions.

Renal and urinary disorders

Less frequent: impairment of renal function including interstitial nephritis or nephrotic syndrome.

Blood and lymphatic system disorders

Less frequent: agranulocytosis and thromobocytopenia.

Investigations

Less frequent: abnormalities of liver function tests.

Special precautions:

FASTUM GEL should be used with caution in patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease, peptic ulceration or a history of such ulceration, renal failure and in those who are receiving coumarin anticoagulants.

FASTUM GEL should not be applied to open wounds or lesions of the skin, or near the eyes.

Do not apply to mucous membranes.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Treatment is symptomatic and supportive.

IDENTIFICATION:

A mucilaginous, colourless, almost transparent gel with an aromatic odour.

PRESENTATION:

Collapsible aluminium tubes of 20 g, 30 g, 50 g and 100 g of **FASTUM GEL**.

Cylindrical polypropylene dispensers of 50 g, and 100 g of **FASTUM GEL**.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Z/3.1/165

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