Impianto definitivo per la stampa
Prodotto F.I. Fastum gel Paese Sud Africa
Codice parte 106758 n.id. 0001/09 Storia modifiche di testo
Codice PF55481G- 55481H- 55481i - 57482E
Sito Produttivo MMLS-FI F.to/Dim. 150x210 mm Laetus 380/10
Colori: nero
Data 18/03/09 Operatore Ordo

SCHEDULING STATUS: S1
PROPRIETARY NAME (and dosage form):

FASTUM® GEL(GEL)

COMPOSITION:
Each 100 g contains:
Ketoprofen 2,5 g (i.e. 2,5 % m/m)
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 below 25 ˚C.
KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBER:
Z/3.1/165
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Adcock Ingram Limited
Adcock Ingram Park
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DATE OF PUBLICATION OF THIS PACKAGE INSERT:
20 July 2005

SKEDULERINGSTATUS: S1
EIENDOMSNAAM: (EN DOSEERVORM)

FASTUM® GEL(JEL)

SAMESTELLING:
Elke 100 g bevat:
Ketoprofeen 2,5 g (i.e. 2,5 % m/m)
FARMAKOLOGIESE KLASSIFIKASIE:
A 3.1 Rumatiekmiddels (antiïnflammatoriese middels)
FARMAKOLOGIESE WERKING:
Ketoprofeen is 'n nie-steroïed antiïnflammatoriese middel.
Aangesien ketoprofeen die sintese van prostaglandien inhibeer, lewer dit antiïnflammatoriese, pynstillende effekte.
FASTUM GEL is ketoprofeen in 'n geskikte mengmiddel wat toelaat dat dit die plek van inflammasie deur middel van die transkutane roete bereik en sodoende lokale behandeling verskaf vir pynlike gewrigte, senings, ligamente en spiere.
INDIKASIES:
Vir die verligting van gelokaliseerde pyn en inflammasie wat met akute muskulo-skeletale beserings gepaard gaan.
KONTRA-INDIKASIES:
Bekende hipersensitiwiteit vir enige van die bestanddele of vir ander middels wat uit 'n chemiese oogpunt, naby verwant is aan ketoprofeen (of ander nie-steroïed antiïnflammatoriese middels, sowel as aspirien en sy derivate).
Veiligheid by kinders is nog nie vasgestel nie.
WAARSKUWINGS:
Die langdurige gebruik van **FASTUM GEL** kan hipersensitiwiteitsreaksies veroorsaak. In sulke gevalle moet behandeling gestaak en 'n geskikte alternatiewe terapie ingestel word. Aangesien die toediening van **FASTUM GEL** fotosensitiwiteit tot gevolg kan hê, moet die behandelde vel nie aan sonlig blootgestel word gedurende behandeling en vir twee weke daarna nie.
INTERAKSIES:
FASTUM GEL moet met versigtigheid gebruik word by pasiënte wat kumarienantistolmiddels ontvang.
SWANGERSKAP EN LAKTASIE:
Veiligheid van **FASTUM GEL** gedurende swangerskap en laktasie is nog nie vasgestel nie.
DOSIS EN GEBRUIKSAANWYSINGS:
Behandeling moet nie 7 dae oorskry nie.
Vir persone van 12 jaar en ouer: Wend een of twee keer per dag aan op die aangetaste plek en masseer liggies in om absorpsie aan te help. Wend 5 tot 15 cm jel met elke toediening aan (100 tot 300 mg ketoprofeen).
NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Indien die baie lae sistemiese absorpsie deur plaaslike aanwending in aanmerking geneem word, word sistemiese newe-effekte nie verwag nie, maar kan nie uitgesluit word nie.
Newe-effekte wat met sistemies-geabsorbeerde ketoprofeen voorkom, sluit in:
Die volgende konvensie is gebruik om die frekwensie van newe-effekte te definieer:
Baie algemeen (>1/10); Algemeen (>1/100, <1/10); Buitengewoon (>1/1 000, <1/100); Seldsaam (>1/10 000, <1/1 000): Uiters seldsaam (<1/10 000) insluitende geïsoleerde gevalle.
Gastroïntestinale afwykings
Seldsaam: gastroïntestinale, peptiese ulserasie en gastroïntestinale bloeding.
Senuweestelselafwykings
Seldsaam: hoofpyn.
Minder dikwels: duiseligheid, senuagtigheid, depressie, slaaploosheid en lomerigheid.
Oor- en labirintafwykings
Minder dikwels: tinnitus.
Immuunsisteemafwykings
Seldsaam: sensitiwiteitsreaksies
Vel en subkutaneuse weefselafwykings
Die volgende newe-effekte is aangemeld, maar die frekwensies daarvan is onbekend: veluitslae en jeuk.
Algemene afwykings en toestande wat verband hou met die plek van toediening
Die volgende newe-effek is aangemeld, maar die frekwensie daarvan is onbekend: edeem.
Oogafwykings
Minder dikwels: belemmerde sig.
Seldsaam: ander okulêre reaksies.
Nier en urinêre afwykings
Minder dikwels: inkorting van nierfunksie insluitend interstisiële nefritis en nefrotiese sindroom.
Bloed en limfatiese sisteemafwykings
Minder dikwels: agranulositose en trombositopenie.
Ondersoeke
Minder dikwels: abnormaliteite van lewerfunksietoetse.
Spesiale voorsorgmaatreëls:
FASTUM GEL moet met sorg gebruik word by pasiënte met asma of brongospasma, bloedingsafwykings, kardiovaskulêre siekte, peptiese ulserasie of 'n geskiedenis van so 'n ulserasie, nierversaking en by diegene wat kumarienantistolmiddels ontvang.
FASTUM GEL moenie op oop wonde en letsels of op die vel of naby die oë aangewend word nie.
Moenie op mukusmembrane aangewend word nie.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Behandeling is simptomaties en ondersteunend.
IDENTIFIKASIE:
'n Slymagtige, kleurlose, byna deurstigtige jel met 'n aromatiese geur.
AANBIEDING:
Opvoubare aluminiumbuise met 20 g, 30 g, en 100 g **FASTUM GEL**.
Silindriese polipropileen resepteerbuis met 50 g en 100 g **FASTUM GEL**.
BERGINGSAANWYSINGS:
Bêre onder 25 ºC.
HOU BUITE BEREIK VAN KINDERS.
REGISTRASIENOMMER:
Z/3.1/165
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Adcock Ingram Limited
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
20 Julie 2005