1.3.2 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still needed to use FASTUM GEL carefully to get the best results from it.

Keep this leaflet. You must need to read it again. Ask your pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve.

SCHEDULING STATUS: **S1**

PROPRIETARY NAME: FASTUM® GEL

(AND DOSAGE FORM) (GEL)

1. WHAT THIS MEDICINE CONTAINS:

Each 100 g contains:

Each 100 g contains:

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

This preparation also contains carbomer 940, ethanol, neroli essence, lavender essence, triethanolamine and purified water.

2. WHAT FASTUM GEL IS USED FOR:

FASTUM gel is used for the relief of localised pain and inflammation associated with acute musculoskeletal injuries.

3. BEFORE USING THIS MEDICINE:

Do not use F AS TUM gel

If you are allergic to any of the ingredients or to other substances that are chemically related to ketoprofen (in particular other nonsteroidal anti-inflammatory medicines such as aspirin and its derivatives).

Take special care with FASTUM gel

If you use FASTUM gel for longer periods you may experience an allergic reaction, in such cases the treatment should be stopped and a suitable alternate therapy instituted.

When using FASTUM gel avoid exposure of the treated skin area to the sun, both during treatment and for two weeks after treatment because F AS TUM gel has the tendency to make the skin sensitive to sunlight.

Do not apply FASTUM gel to mucous membranes (the moist linings of the body cavities e.g. inside of the mouth or nasal passages), open wounds or lesions of the skin, or near the eyes.

If you suffer from asthma or bronchospasm. bleeding disorders, cardiovascular disease, kidney failure, stomach and duodenal ulceration or have a history of such ulceration, use FASTUM gel with caution.

If you are receiving medication that prevents the blood from clotting, please use FASTUM gel with caution.

Safety in children has not been established.

Pregnancy and breastfeeding

Safety of FASTUM gel during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby while using FASTUM gel, please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE THIS MEDICINE:

Always use FASTUM gel as your doctor or pharmacist has instructed you. You should check with your pharmacist or doctor if you are unsure.

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 em of gel with each application (100- 300 mg ketoprofen).

Do not share this medicine with others.

If you have the impression that the effect of FASTUM gel is too strong or too weak, talk to your doctor or pharmacist.

5. SIDE EFFECTS:

Considering that the absorption of **FASTUM gel** throughout the body is very low after topical application, side effects affecting the rest of the body are not expected, but cannot be excluded.

Side effects experienced when ketoprofen is absorbed throughout the body include:

Stomach and duodenal ulceration, internal bleeding of the stomach and intestines, headache, dizziness, nervousness, skin rashes, itching, ringing in the ears, swelling due to retained fluid, depression, drowsiness, inability to sleep, blurred vision and other ocular reactions.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORAGE AND DISPOSAL INFORMATION:

Store at or below 25°C.

Store all medicines out of reach of children.

Do not use after expiry date stated on the carton and tube.

Do not dispose of unused medicine in drains or sewerage systems. Return all unused medicine to your pharmacist.

7. 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**.

8. IDENTIFICATION:

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

9. REGISTRATION NUMBER:

Z/3.1/165

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF

REGISTRATION:

Adcock Ingram Limited

New Road 1

Erand Gardens

Midrand, 1685

Private Bag X69

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