SUMMARY OF PRODUCT CHARACTERISTICS

IBUMEX GEL

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1. Name of the medicinal product

a) Proprietary name of a medicine

Ibumex Gel

b) Approved generic name(s)

Ibuprofen BP

2 Qualitative and quantitative composition

Ibuprofen 5.0% w/w

For Excipients 6.1

3 Pharmaceutical form Dosage form

Gel

4 Clinical particulars

4.1 Therapeutic indication(s)

Ibumex gel is a topically applied analgesic and non-steroidal anti-inflammatory agent used for the fast relief of pain associated with backache, strains, sprains, muscular and rheumatic aches

4.2 Posology and method of administration

Posology

Adults, the elderly, and children over 12 years: Squeeze 2 to 5cm (i.e. 0.8 to 2 inches) of gel (50mg to 125 mg ibuprofen) from the tube and lightly rub into the affected area until absorbed. Use up to four times daily with individual doses administered at least 4 hours apart. Patients should not apply more than 500mg ibuprofen (approximately 5g gel) in any 24 hour period.

Wash hands after each application. Review treatment after 2 weeks, especially if the symptoms worsen or persist.

Children under 12 years: Do not use on children 12 years of age, except on the advice of a doctor.

Method of administration.

For cutaneous use.

4.3 Contra-indications

Not to be used if allergic to any of the ingredients, or in cases of hypersensitivity to aspirin, ibuprofen or related painkillers (including when taken by mouth), especially where associated with a history of asthma, rhinitis or urticaria.

Not to be used on broken or damaged skin.

***4.4* Special warnings and precautions for use**

Apply with gentle massage only.

Discontinue if rash develops.

Hands should be washed immediately after use.

Not for use with occlusive dressings.

Keep away from the eyes and mucous membranes.

Oral NSAIDs, including ibuprofen, can sometimes be associated with renal impairment, aggravation of active peptic ulcers, and can induce allergic bronchial reactions in susceptible asthmatic patients.

Although systemic absorption of topically applied ibuprofen is less than for oral dosage forms, these complications can occur in rare cases. For these reasons, patients with an active peptic ulcer, a history of kidney problems, asthma or intolerance to aspirin or ibuprofen taken orally should seek medical advice before using the gel as should patients already taking other painkillers.

4.5 Interactions

Non-steroidal anti-inflammatory drugs may interact with blood pressure lowering drugs, and may possibly enhance the effects of anticoagulants, although the chance of either of these occurring with a topically administered preparation is extremely remote.

Where aspirin or other NSAID tablets are taken concurrently, it is important to bear in mind that these may increase the incidence of undesirable effects.

4.6 Pregnancy and lactation

Not to be used during pregnancy or lactation.

Pregnancy:

Although no teratogenic effects have been demonstrated, ibuprofen should be avoided during pregnancy. The onset of labour may be delayed and the duration of labour increased.

Lactation:

Ibuprofen appears in breast milk in very low concentrations but is unlikely to affect breast fed infants adversely.

Effects on the ability to drive and operate machinery

None known

4.6 Undesirable effects:

Very rarely, susceptible patients may experience the following side effects with ibuprofen, but these are extremely uncommon when ibuprofen is administered topically. If they occur, treatment should be discontinued:-

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis (b) respiratory tract reactivity comprising of asthma, aggravated asthma, brochospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritis, urticaria, purpura, angioedema and less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Gastro-intestinal: Side effects such as abdominal pain and dyspepsia have been reported.

Renal: Renal impairment can occur in patients with a history of kidney problems.

4.7 Overdose

Overdosage with a topical presentation of ibuprofen is extremely unlikely.

Symptoms of severe ibuprofen overdosage (eg following accidental oral ingestion) include headache, vomiting, drowsiness and hypotension. Correction of severe electrolyte abnormalities should be considered.

5 Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: M02AA13, Anti-inflammatory preparations, non-steroids for topical use.

Ibuprofen 10% w/w Gel is a topical preparation which has anti-inflammatory and analgesic properties. It contains the active ingredient, ibuprofen, which exerts its effects directly in inflamed tissues underlying the site of application, mainly by inhibiting prostaglandin biosynthesis.

Because it is formulated in an aqueous/alcoholic gel, the preparation also exerts a soothing and cooling effect when applied to the affected area.

5.2 Pharmacokinetic properties

Specially formulated for external application, the active ingredient penetrates through the skin rapidly and extensively (approximately 22% of a finite dose within 48 hours), achieving high, therapeutically relevant local concentrations in underlying soft tissues, joints and the synovial fluid, whilst producing plasma levels that are unlikely to be sufficient to cause any systemic side-effects, other than in rare individuals who are hypersensitive to ibuprofen. Furthermore, there do not appear to be any appreciable differences between the oral and topical routes of administration regarding metabolism or excretion.

5.4 Preclinical safety data

No special information

6 Pharmaceutical particulars

6.1 List of excipients

Disodium Hydrogen Phosphate Dodecahydrate

Citric Acid Anhydrous

Methyl Paraben

Propyl Paraben

Carbomer (Carbopol 2001)

Propylene Glycol

Alcohol 90% (Rectified spirit)

Menthol

Triethanolamine

6.2 Incompatibilities - None known.

6.3Shelf-life -

- **In the original unopened container;** 36 months

- **After reconstitution (where appropriate)** NA
- **Shelf-life after first opening:** Not applicable

Special precautions for storage:

Intamine should be stored below 25^{O}C, in a dry and dark place.

Keep out of the reach of children

6.4 **Nature and composition of containers**

Pack Size: 25g. Ibumex Gel aluminum Tubes, Ibumex Gel Leaflets, Ibumex Gel unit cartons,

Instruction for use/handling

For external use only

Wash hands before and after use.

Restriction on sale / distribution:

Prescription only medicine (POM)

7 Administrative data

i. **Name and address of holder of a registration.**

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8.i Registration number. – H2000/0250

ii. Date of first registration- 20/07/2000