SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen 5% w/w gel

AUXIFEN 5% w/w Gel

Tesco Health Ibuprofen 5% w/w gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of gel contains 50 mg (5%) ibuprofen

Excipient(s) with known effect: propylene glycol, ethanol.
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Gel
Clear gel

m1-3-1-04-1-therapeutic-indications

4.1. Therapeutic indications

Topical analgesic and anti-inflammatory for backache, rheumatic and muscular pain, sprains and sports injuries

4.2. Posology and method of administration

Posology

For adults, the elderly and children over 12 years

Method of administration

Apply the gel over the affected area and massage gently until absorbed.

Repeat as necessary, up to a maximum of three times a day. Not to be repeated more frequently than every four hours.
For each application use about 10 to 40mm (½ to 1½ inches) of the gel (containing about 50 to 125mg Ibuprofen).
If no improvement is seen after two weeks, consult your doctor.

For external use only.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Those patients known to be hypersensitive to ibuprofen, or any of the ingredients or sensitive to aspirin, or other NSAIDS including when taken by mouth, or asthmatic patients in whom aspirin or non-steroidal anti-inflammatories are known to precipitate asthmatic attacks, rhinitis or urticaria. Use on broken skin or denuded skin. Simultaneous use on the same site with any other topical medicine. Use in the presence of local infection. Use in the last trimester of pregnancy**.**

4.4 Special warnings and precautions for use

Paediatric population
Not recommended for children under 12 years of age

The gel should not be used on or near mucous membranes, nor near the eyes.

Avoid contact with inflamed or broken skin. Discontinue use if rash or irritation develops. Not for use with occlusive dressings.

Always try on a small area first.

As it is known that oral Ibuprofen may worsen an existing renal impairment, or aggravate an active peptic ulcer, patients with a history of renal problems or with an active peptic ulcer should seek medical advice before using topical Ibuprofen products such as Ibuprofen Gel.

Ibuprofen Gel contains propylene glycol which may cause skin irritation and ethanol which may cause burning sensation on damaged skin.

The hands should be washed after applying the product, unless they are being treated.

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. If there is no improvement, or the condition is aggravated, the doctor should be consulted.

By extrapolation from other routes of administration:
Although this is less likely with NSAIDs intended for topical use compared to oral drugs, the use of Ibuprofen Gel, as with any drug known to inhibit cyclo-oxygenase/prostaglandin synthesis, may impair fertility. In women who have difficulty conceiving or who are undergoing investigation of infertility, withdrawal of Ibuprofen Gel should be considered.

If anyone swallows the gel he or she should contact his or her doctor or nearest casualty department.

Keep all medicines out of the sight and reach of children.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Severe cutaneous adverse reactions (SCARs) Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen (see section 4.8). Most of these reactions occurred within the first month.

If signs and symptoms suggestive of these reactions appear, ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate)

4.5. Interactions with other medicinal products and other forms of interaction

No interaction studies have been performed.

Concurrent use of aspirin or other NSAIDS may result in an increased incidence of adverse reactions. Due to the low systemic absorption in normal conditions, interactions described for NSAIDS administered orally are unexpected.

4.6. Fertility, Pregnancy and lactation

There are no clinical data from the use of topical forms of ibuprofen during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic ibuprofen exposure reached after topical administration can be harmful to an embryo/foetus. During the first and second trimester of pregnancy, ibuprofen gel should not be used unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.
During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors including ibuprofen may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed. Therefore, ibuprofen is contraindicated during the last trimester of pregnancy (see Section 4.3)

4.7. Effects on ability to drive and use machines

No effects are known with topical Ibuprofen. Ibuprofen Gel has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Skin disorders are most frequently reported: Application site reactions such as, rashes, pruritus and urticaria**,** drying, reddening, burning sensation, contact dermatitis. Photosensitivity reactions – frequency unknown.

Other systemic undesirable effects of NSAIDs depend on the quantity of gel applied, the treated area, the integrity of the skin, the duration of treatment, the use of occlusive dressings: although extremely uncommon when administered topically side effects such as abdominal pain, dyspepsia and renal impairment are possible.

Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of:

(a) Non-specific allergic reactions and anaphylaxis.
(b) Respiratory tract reactivity comprising of asthma, aggravated asthma, dyspnoea and bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease (see section 4.3).
(c) Assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdosage is unlikely to occur with topical application.

Symptoms of Ibuprofen overdose include headache, vomiting, drowsiness and hypotension.

Severe electrolyte abnormalities should be corrected.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code M02AA13

Anti-inflammatory preparations, non-steroidals for topical use – ibuprofen.

When administered as a topical preparation ibuprofen has been shown to be an effective anti-inflammatory and analgesic for the rapid symptomatic relief of superficial musculoskeletal disorders including rheumatic and muscular pain, backache, sprains, strains, lumbago and fibrositis by virtue of percutaneous absorption.

5.2 Pharmacokinetic properties

Ibuprofen is applied topically for percutaneous absorption. When applied topically, absorption through the skin has been shown to be about 5% of that taken orally. Systemic concentration reaches a maximum of about 0.6 micrograms per ml some two hours after application.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, ibuprofen is devoid of mutgenic activity in vitro and in vivo.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol

Diisopropanolamine

Carbomer

Denatured Ethanol

Purified water

6.2 Incompatibilities

Not applicable to a topical formulation.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Collapsible aluminium tube with epoxy resin lining and high density polyethylene cap filled to an average weight of 15, 35, 50 or 100g. The tube is enclosed by a cardboard carton containing package insert.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

The Mentholatum Company Limited

1 Redwood Avenue

Peel Park Campus

East Kilbride G74 5PE, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00189/0024

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

Date of first authorisation: 21 May 1996
Date of latest renewal: 15 Feb 2009

10 DATE OF REVISION OF THE TEXT

05/09/2024