SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Radian B Anti-Inflammatory Ibuprofen 5% w/w Gel
Care Ibuprofen 5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 5.0%w/w

Excipient(s) with known effect

Benzyl Alcohol 1.0% w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel for topical application

4 CLINICAL PARTICULARS

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

Strength 5% maximum

Method of Administration

For topical application to the skin

Dosage

Adults, the elderly and children over 14 years:

Squeeze 5 to 10cm of the gel (containing 50 to 100mg of ibuprofen) from the tube and lightly rub into the affected area until absorbed.

The dose should not be repeated more frequently than every four hours and no more than 4 times in any 24 hour period.

Wash hands after each application. Do not exceed the stated dose. Unless recommended by a doctor advice should be sought about continued treatment if symptoms persist for more than 2 weeks.

Children under 14 years: Do not use on children under 14 years of age except on the advice of a doctor.

4.3 Contraindications

Hypersensitivity to ibuprofen or any of the excipients in the product.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to aspirin or other NSAIDs.

Patients suffering from renal failure.

Third trimester of pregnancy.

4.4 Special warnings and precautions for use

Apply with gentle massage only. Avoid contact with eyes, mucous membranes and inflamed or broken skin.

Discontinue if rash develops.

Hands should be washed immediately after use.

Not for use with occlusive dressings.

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 the 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 a history of kidney problems, an active peptic ulcer, asthma or intolerance to aspirin or ibuprofen should seek medical advice before using Radian B Ibuprofen 5% w/w Gel.

Avoid excessive sunlight exposure on the treated area as this may possibly lead to photosensitisation.

Keep 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), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome), and acute generalised 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).

Ingredients with specified warnings

This medicine contains 1% w/w Benzyl Alcohol which may cause mild local skin irritation (allergic reactions).

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of aspirin or other NSAIDs may result in an increased incidence of adverse reactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no clinical data from the use of topical forms of Ibuprofen Gel during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic Ibuprofen Gel exposure reached after topical administration can be harmful to an embryo/fetus. 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 Gel 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 Gel is contraindicated during the last trimester of pregnancy (see Section 4.3)

Not to be used during pregnancy or lactation. Whilst no teratogenic effects have been demonstrated in animal experiments, Ibuprofen should be avoided during pregnancy. The onset of labour may be delayed and duration of labour increased. Ibuprofen appears in breast milk in very low concentration and is unlikely to affect the breast fed infant adversely.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Skin disorders are most frequently reported.

Skin and subcutaneous tissue disorders

Application site reactions, rashes, pruritis, and urticaria.

Very rare: Severe cutaneous adverse reactions (SCARs) (including Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis).

Frequency not known: Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), acute generalised exanthematous pustulosis (AGEP), photosensitivity reactions.

Gastro-intestinal: abdominal pain, dyspepsia.

Respiratory: bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

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, bronchospasm 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).

Other adverse effects reported very rarely include renal failure.

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

4.9 Overdose

Overdosage with a topical presentation of ibuprofen gel is unlikely; however, it may be encountered following excessive use or accidental ingestion.

In children ingestion of more than 400mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.

Symptoms

Most patients who have ingested or been exposed to clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management

Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ibuprofen is a non-steroidal anti-inflammatory drug which has been tested and proved to be effective as an analgesic, anti-pyretic and anti-inflammatory after systemic administration. When administered as a topical preparation ibuprofen has been shown to be an effective topical analgesic and anti-inflammatory for the relief of rheumatic and muscular pain, backache, sprains, strains, lumbago and fibrositis by virtue of precutaneous absorption.

Radian B Ibuprofen Gel or Care Ibuprofen 5% Gel is a clear odourless gel. Following application to the affected area, it initially feels cool to the skin and is free from skin warming effects.

5.2 Pharmacokinetic properties

The gel product containing ibuprofen diffuses through the skin as a function of time and after 24 hours an application to human skin shows that the dose administered is present in the epidermis and dermis. Percutaneous absorption of this 5% ibuprofen gel is approximately 5% that of oral ibuprofen. Therapeutic concentrations are reached locally but not systemically.

5.3 Preclinical safety data

There are no new data published on the active ingredient.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxyethylcellulose

Sodium Hydroxide

Benzyl Alcohol

Isopropyl Alcohol

Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months – Aluminium Tube

6.4 Special precautions for storage

Store below 25ºC. Replace cap tightly after use.

6.5 Nature and contents of container

Aluminium tube with internal epoxy phenolic coating containing 30g, 50g or 100g of Ibuprofen Gel

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

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HD7 5QH

United Kingdom

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