

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Phorpain 5% w/w Gel Ibuprofen.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5% w/w Ibuprofen.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

A clear, colourless and smooth gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For local symptomatic relief of pain and inflammation in the trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism.

4.2 Posology and method of administration

Posology

Adults: Apply a thin layer of gel to the affected area. Massage gently until absorbed. Repeat as necessary up to three times a day.

Wash hands after each application. Do not exceed the stated dose.

Review treatment after 2 weeks, especially if the symptoms worsen or persist.

Elderly: Although there is a low systemic exposure, Phorpain gel should be used with caution in elderly patients who may be more prone to adverse events.

Pediatric population: Not recommended for use on children under the age of 12 years.

Method of administration:

For topical application to the skin.

4.3 Contraindications

Hypersensitivity to the active substance or any other non-steroidal anti-inflammatory drugs (aspirin) or any of the excipients listed in section 6.1. Patients with bronchospasm, asthma, rhinitis or urticaria.

Not to be used on broken or damaged skin.

4.4 Special warnings and precautions for use

Patients should seek medical advice if symptoms worsen or persist.

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, waterproof protective dressings should not be used over treated areas and patients with asthma, an active peptic ulcer or a history of kidney problems, should seek medical advice before using the gel, as should patients already taking other painkillers.

Keep away from the eyes and mucous membranes. This product should not be used with occlusive dressings.

4.5 Interaction with other medicinal products and other forms of interaction

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

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelets aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding the extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 5.1)

4.6 Fertility, pregnancy and lactation

Pregnancy

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.

Breast-feeding

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

Not relevant.

4.8 Undesirable effects

The side effects listed in the table below have been reported with the following frequency:

Uncommon ($\geq 1/1,000$ to $< 1/100$) Very rare ($< 1/10,000$)

Not known (cannot be estimated from the available data)

System organ class	Frequencies	Undesirable effect
Immune system disorders	Very rare	Hypersensitivity ¹
Respiratory, thoracic and mediastinal disorders	Not known	Bronchospasm in patients suffering from or with a previous history of bronchial asthma or allergic disease
Gastrointestinal disorders	Not known	Abdominal pain, dyspepsia
Skin and subcutaneous tissue disorders	Uncommon	Skin rashes, itching, irritation
Renal and urinary disorders	Not known	Renal impairment

¹These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, or (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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Overdose with a topical presentation of Phorpain Ibuprofen 5% w/w Gel is unlikely.

Symptoms

Symptoms of ibuprofen overdose include headache, vomiting, drowsiness and hypotension. Correction of severe electrolyte abnormalities should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory preparations, non-steroids for topical use.

ATC code: M02A A13

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 mild to moderate arthritic pain, muscular pain, backache, sprains, strains, lumbago and fibrositis by virtue of percutaneous absorption.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelets aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 h before or within 30 min after immediate release aspirin dosing (81mg), a decreased effect of ASA on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

5.2 Pharmacokinetic properties

Specially formulated for external application, the active ingredient penetrates through the skin rapidly and extensively, 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.

5.3 Preclinical safety data

Published information on subchronic toxicity studies confirms that topically applied ibuprofen is well tolerated both locally and by the gastro-intestinal tract. Any local erythema is only mild and no signs of mucosal lesions or ulcerogenic effects have been determined in the gastro-intestinal tract.

In the course of assessing mucosal tolerance, topical ibuprofen has been found to cause acute but reversible, irritant reactions in the eyes and mucous membranes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hyetellose/hydroxyethylcellulose
Sodium Hydroxide (E524)
Benzyl Alcohol
Isopropyl Alcohol
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

In use shelf life: Discard within 30 days after first opening.

6.4 Special precautions for storage

Do not store above 25°C. Keep the tube tightly closed.

6.5 Nature and contents of container

Aluminium tube with internal epoxy phenolic coating and a polyethylene screw cap containing 30 g of Ibuprofen 5% w/w Gel.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals Ltd
Capital House
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London EC4N 7BL
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8 MARKETING AUTHORISATION NUMBER

PA0899/004/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th November 2011

Date of last Renewal: 18th November 2016

10 DATE OF REVISION OF THE TEXT

May 2018