Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Phorpain 5% w/w gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 5% w/w
Excipient(s) with known effect
Each 100mg of gel contains 1mg of Benzyl alcohol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

Clear, colourless 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 maybe 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 of the excipients listed in section 6.1.
Hypersensitivity to any other non-steroidal anti-inflammatory drugs (aspirin)
Patients with bronchospasm, asthma, rhinitis or urticaria.
Not to be used on broken or damaged skin.
Third trimester of pregnancy

4.4 Special warnings and precautions for use

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If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate).

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.

This medicine contains 1.25 mg benzyl alcohol in each 125mg, which is equivalent to 0.01mg/mg. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicine contains less than 1 mmol sodium (23 mg) per 125mg, that is to say essentially 'sodium-free'.

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 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

Not to be used during pregnancy or lactation.

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

Breast-feeding
Ibuprofen appears in breast milk in very low concentration and is unlikely to affect the breast fed infant adversely.

Fertility
No data available

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 (≥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	Hypersensivity[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
	Very rare	Severe cutaneous adverse reactions (SCARs) (including Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis)
	Not known	Photosensitivity reactions, Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP)
Renal and urinary disorders	Not known	Renal impairment

1 These 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
Website: www.hpra.ie.

4.9 Overdose

Overdose with a topical presentation of Phorpain Gel is unlikely.

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

Management
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.

Clinical efficacy and safety
Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet 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

Absorption and Distribution
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.

Biotransformation and Elimination
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

Hydroxyethyl cellulose
Sodium Hydroxide
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 cap tightly closed.

6.5 Nature and contents of container

Aluminium tube with internal epoxy phenolic coating containing 30g or 100g of Phorpain 5% w/w Gel. The tube is closed with a polypropylene cap.

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

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

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA1142/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th November 1997
Date of last renewal: 14th November 2007

10 DATE OF REVISION OF THE TEXT

December 2025