

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Phorpain 5% w/w Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 5% w/w

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel

Clear colourless gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Topical analgesic and anti-inflammatory for backache, rheumatic and muscular pain, sprains, strains and neuralgia.

4.2 Posology and method of administration

Method of administration

For topical application to the skin.

Dosage:

Adults: Apply a thin layer of the 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 prone to adverse events.

Children: Not recommended for use on children under the age of 14 years.

4.3 Contraindications

Patients with hypersensitivity to ibuprofen or any of the excipients of Phorpain 5% w/w Gel, aspirin or other NSAIDs.

Patients with asthma, rhinitis or urticaria.

4.4 Special warnings and precautions for use

Not to be applied to broken skin, lips or near eyes, on the genital area.

Do not apply a dressing to the same area after using this medicine.

Application over extensive areas for prolonged periods or application in excess of recommended dosage may potentially give rise to systematic effects which include gastrointestinal disturbances, bleeding, irritability, fluid retention, rash, hepatitis, renal dysfunction, anaphylaxis, and rarely blood dyscrasias, bronchospasm and erythema multiforme.

This product should be used with great caution in patients with a history of peptic ulcer, gastrointestinal bleeding, hepatic or renal insufficiency, or bleeding diathesis, or intestinal inflammation. Circulating levels of the active drug substance are low but the theoretical increased risk in these patients should be considered.

4.5 Interaction with other medicinal products and other forms of interactions

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 platelet 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 Pregnancy and lactation

Phorpain 5%Gel should not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Respiratory: bronchospasm may be precipitated in patients suffering from or with a

previous history of bronchial asthma or allergic disease.

Gastro-intestinal: abdominal pain, dyspepsia.

Skin disorders are most frequently reported.

Skin: application site reactions, rashes, pruritus, urticaria, burning sensation and sore or weeping spots.

4.9 Overdose

Overdosage with a topical presentation of Phorpain Gel is unlikely.

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 and antirheumatic products, non-steroids, propionic acid derivatives.

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 rheumatic and 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 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

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

Animal irritancy (including phototoxicity) and absorption studies have been carried out. There is no new data published on the active ingredient per se.

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 polyethylene cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

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

7. MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Ltd,
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8. MARKETING AUTHORISATION NUMBER

PA 899/4/2

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 14th November 1997

Date of last renewal: 14th November 2002

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03/05/2011