Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pruridene 1 mg/g Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains 1 mg of dimetindene maleate.

Excipient(s) with known effect: benzalkonium chloride and propylene glycol.
Each g of gel contains 0.05 mg of benzalkonium chloride and 150 mg of propylene glycol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel
Colourless, clear to slightly opalescent homogeneous gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated in adults, the elderly and children aged 2 years or over for the short-term symptomatic relief of pruritus associated with minor inflammatory skin conditions, such as bites, stings, hives, and contact dermatitis.

4.2 Posology and method of administration

Posology
Children, adults, elderly:
Pruridene Gel should be applied in a thin layer to the affected and itchy area of the skin 2-4 times a day.
The patient should be advised to see a doctor if there is no improvement or worsening after using Pruridene Gel for 3 days.
The maximum duration of treatment without consulting a doctor is 7 days.

Paediatric population
Not to be used in children under 2 years of age.
Avoid use to large areas of skin in younger children (see section 4.4).

Method of administration
Cutaneous use.
Occlusive dressings or bandages should not be used with this product.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Pruridene Gel should not be used on large areas of the skin, particularly if broken, especially in children and pregnant or breastfeeding women.

In case Pruridene Gel be applied to large areas of skin, prolonged exposure of treated areas to sunlight should be avoided.

Excipients
This medicinal product contains 0.05 mg benzalkonium chloride in each g of gel. Benzalkonium chloride may irritate the skin. Use during pregnancy and lactation is not expected to be associated with harmful effects to the mother as cutaneous

absorption of benzalkonium chloride is minimal. However, this medicine should not be applied to the breasts including nipples if the patient is breast-feeding because the baby may take it in with milk. Not for application to mucosa.

This medicinal product contains 150 mg propylene glycol in each g of gel. Propylene glycol may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. Due to low systemic absorption of dimetindene maleate its interaction with other medicinal products and other forms of interaction are not expected.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data from the use of dimetindene maleate in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). Dimetindene maleate should be used in pregnant women only if the benefit to the mother outweighs the risk to the foetus.

In pregnancy the medicinal product should not be applied to large areas of skin, especially in cases of broken skin.

Breastfeeding
While breast-feeding, the medicinal product should not be applied to large areas of skin especially in cases of broken skin. The gel must not be applied to the nipples while breast-feeding.

Fertility
No data are available on the effects on human fertility. Animal studies do not indicate any effect on fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Pruridene Gel has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The most frequently reported adverse reactions during treatment are mild and transient skin reactions at the application site.

The following categories have been used for classification of the frequency of undesirable effects:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Skin and subcutaneous tissue disorders
Not known: skin burning sensation, dry skin, allergic dermatitis

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 directly to HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

Symptoms
There are no data about overdose of the product applied topically to the skin.

Accidental swallowing of a considerable amount of dimetindene maleate may induce some symptoms characteristic to overdose of H_1 antihistamines: CNS depression with drowsiness (mainly in adults), CNS stimulation and antimuscarinic effects (especially in children), including excitement, ataxia, hallucinations, tonic-clonic spasms, mydriasis, dry mouth, flushed face, urinary retention and fever. Hypotension may also occur.

Management
There is no specific antidote for overdose of antihistamines. In such cases, should be used the typical procedure involving induced vomiting or gastric lavage (if induced vomiting proves to be ineffective), administration of activated charcoal, laxatives.

If necessary, measures supporting vital functions (breathing and circulation) should be used. Do not use drugs from the group of analeptics. If hypotension occurs, medicinal products that increase blood pressure (vasoconstrictors) can be administered

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for the topical use, ATC code: D04AA13

Mechanism of action and pharmacodynamic effects
Dimetindene maleate is a histamine H_1-receptor antagonist. It presents a high binding affinity for these receptors. It considerably reduces the hyperpermeability of the capillaries which is associated with immediate hypersensivity reactions. When topically applied, dimetindene maleate also presents local anaesthetic properties.

Dimetindene maleate is effective against pruritus of various origins and rapidly relieves itching and irritation. The gel base facilitates the penetration of the active ingredient into the skin.

5.2 Pharmacokinetic properties

Dimetindene maleate in gel penetrates rapidly into the skin and exerts its antihistaminic effect within a few minutes. The effect reaches its maximum after 1 to 4 hours.

Following topical application in healthy volunteers, the systemic availability of dimetindene maleate is approximately 10% of the dose applied.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity.

Studies in laboratory animals (rats and rabbits) have shown no teratogenic properties of dimetindene maleate. Dimetindene maleate in rats did not influence fertility nor the peri-and postnatal development of the offspring at doses 250 times higher than the human dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer (type 974 P)
Disodium edetate
Sodium hydroxide
Propylene glycol (E1520)
Benzalkonium chloride
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years
Shelf-life after first opening: 3 months.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Aluminium tube with an internal epoxy-phenolic coating and a high-density polyethylene screw cap.
Tube: 30 g or 50 g gel.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Citrine Healthcare Limited
Orchard Road
Clondalkin
Dublin 22
D22 V4H1
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23214/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th August 2024

10 DATE OF REVISION OF THE TEXT