1. NAME OF THE MEDICINAL PRODUCT

Permethrin Cream 5% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains:
Permethrin BP.....5.00% w/w
Preservative:
Formaldehyde Solution BP.....0.1% w/w
Cream Base.....q.s.

3. PHARMACEUTICAL FORM

Cream.

3.1 Physical Description: White to off-white, smooth, homogeneous cream, free from foreign particulate matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Permethrin Cream 5% w/w is indicated for the treatment of:

- Scabies infestation caused by *Sarcoptes scabiei*.
- Pediculosis pubis (crab lice infestation).

4.2 Posology and Method of Administration

Route of Administration: Cutaneous use only.

Adults and Elderly

Apply a thin layer of cream to the entire body from the neck down, paying particular attention to skin folds, wrists, hands, finger webs, under fingernails, buttocks, genital areas, ankles and feet.

In elderly patients, the cream should also be applied to the neck, scalp, hairline, temples and forehead, avoiding the area around the eyes and mouth.

Leave on the skin for 8–12 hours (usually overnight), then wash thoroughly.

A single application is usually sufficient. If live mites are observed after 7–14 days, a second application may be made.

Paediatric Population
Children older than 2 months should receive treatment under adult supervision.

The cream should be applied to the entire body, including the scalp, neck, forehead, temples and ears while avoiding the eyes and mouth.

Safety and efficacy in infants below 2 months have not been established.

4.3 Contraindications

- Hypersensitivity to permethrin, pyrethroids, pyrethrins or any of the excipients.
- Known allergy to any component of the formulation.

4.4 Special Warnings and Precautions for Use

- For external use only.
- Avoid contact with eyes, nose, mouth and mucous membranes.
- If accidental contact occurs, rinse thoroughly with water.
- Temporary itching may persist after successful treatment and does not necessarily indicate treatment failure.
- Household members and close contacts should be treated simultaneously to reduce the risk of reinfestation.
- Clothing, bedding and towels used by the patient should be washed thoroughly before reuse.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

No clinically significant interactions have been reported.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

Limited data indicate no harmful effects during pregnancy. Use only when clearly needed and under medical supervision.

Lactation

Permethrin is minimally absorbed through the skin. Use during breastfeeding only when clinically indicated. Avoid application to the breast area immediately before feeding.

Fertility

No adverse effects on fertility have been observed in animal studies.

4.7 Effects on Ability to Drive and Use Machines

Permethrin Cream has no or negligible influence on the ability to drive and operate machinery.

4.8 Undesirable Effects

The following adverse reactions may occur:

Common:

- Pruritus
- Mild burning sensation
- Erythema
- Skin irritation
- Dry skin

Uncommon/Rare:

- Rash
- Paraesthesia
- Contact dermatitis
- Allergic skin reactions

4.9 Overdose

Overdose following topical administration is unlikely.

In cases of accidental ingestion, symptomatic and supportive treatment should be instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic Group: Ectoparasiticides, pyrethrins including synthetic compounds.
ATC Code: P03AC04

Permethrin is a synthetic pyrethroid with potent acaricidal and pediculicidal activity. It acts by disrupting sodium ion transport through nerve cell membranes of parasites, causing delayed repolarization, paralysis and death.

5.2 Pharmacokinetic Properties

Percutaneous absorption following topical application is minimal.

Absorbed permethrin is rapidly metabolized by ester hydrolysis and excreted primarily in the urine as inactive metabolites.

5.3 Preclinical Safety Data

Preclinical studies reveal no special hazards for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, reproductive toxicity and carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Typical excipients may include:

- Cetostearyl Alcohol
- Liquid Paraffin
- White Soft Paraffin
- Isopropyl Myristate
- Emulsifying Wax
- Glycerin
- Purified Water
- Preservatives (where applicable)

6.2 Incompatibilities

Not known.

6.3 Shelf Life

24 months.

6.4 Special Precautions for Storage

Store below 30°C.

Protect from excessive heat.

Keep out of the reach and sight of children.

6.5 Nature and Contents of Container

Permethrin Cream 5% w/w is packed in a laminated tubes containing 30g.

6.6 Special Precautions for Disposal and Other Handling

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

7. MARKETING BY

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8. MANUFACTURED BY:

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