PERMETHRIN CREAM 5% w/w

30 gm

PERMETHRIN CREAM
5% w/w

Composition
Permethrin BP ..... 5% w/w
Cream base ..... q.s.

To be applied as directed by the Physician.

Storage :
Store below **30**°C.
Protect from light and heat.

FOR EXTERNAL USE ONLY

Keep out of the reach of children.

PERMETHRIN CREAM
5% w/w

30 gm

PERMETHRIN CREAM 5% w/w

Re-place cap tightly after use.

Manufactured by:
Kwality Pharmaceuticals Ltd.
Nag Kalan, Majitha Road,
Amritsar - 143601 (INDIA)

Mfg. Lic No.: 1800-OSP

Batch No. :

Mfg. Date :

Exp. Date :

NAFDAC REG. NO:

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS PRODUCT INFORMATION

1. Name of Product: Permethrin Cream 5% w/w

1.1 (Trade) Name of Product: Permethrin Cream 5% w/w

1.2 Strength (formula): 5% w/w

1.3 Pharmaceutical Dosage Form: Cream

2. Qualitative and quantitative compositions:

2.1 Qualitative Composition Declaration: Permethrin

2.2 Quantitative Composition Declaration:

Sl. No.	Composition (INN)	Concentration in mg	Active / Inactive Ingredients
1.	Permethrin	50.000	Active Ingredient
2.	Butylated Hydroxytoluene	0.100	Inactive
3.	Carbomers	10.00	Inactive
4.	Coconut Oil	20.000	Inactive
5.	Glycerol	90.000	Inactive
6.	Glycerol Monostearate	10.000	Inactive
7.	Liquid Paraffin	20.000	Inactive
8.	Sodium Hydroxide	1.875	Inactive
9.	Formaldehyde	1.000	Inactive
10.	Purified Water	793.275	Inactive

3. Pharmaceutical Form: It should be white to off white colored cream.

4. Clinical Particulars:

4.1 Therapeutic Indications:

Permethrin Dermal Cream is indicated for the treatment of scabies and crab louse infestations in adults and children > 2 months of age.

4.2 Posology and method of administration:

Permethrin Dermal Cream is suitable for use by adults and children of 2 months of age and above.

Permethrin Dermal Cream is also suitable for use by the elderly.

Keep this medicine out of sight and reach of children.

Permethrin Dermal Cream should be applied to clean, dry, cool skin. If the patient has taken a warm bath prior to treatment the skin should be allowed to cool before the cream is applied.

Permethrin Dermal Cream is a vanishing cream and when rubbed gently into the skin it will disappear. Therefore, there is no need to continue to apply cream to the skin until it remains detectable on the surface.

Older children should be supervised by an adult when applying the cream to ensure that a thorough treatment is administered.

Treatment of Scabies

Posology

Unless otherwise directed by the physician, the recommended dosage is as follows:

Adults and adolescents over 12 years of age:

Apply up to 30 g of cream (corresponding to one 30 g tube).

Children aged from 2 months-5 years:

Up to 7.5 g of cream (corresponding to ¼ of a 30 g tube).

The safety and efficacy of Permethrin in children under 2 months of age have not been established. No data are available.

Method of Administration

For cutaneous use only.

The medicinal product must not be swallowed.

Carefully apply a thin layer of cream to the skin (cutaneous use).

Adults should apply the cream uniformly to the whole body including the neck, palms of the

hands and soles of the feet. The head and face can be spared unless scabies efflorescences are present in this region.

On application, the areas between the fingers and toes (also under the finger and toe-nails), the wrists, elbows, armpits, external genitalia and the buttocks should be especially carefully treated. In cases where the head, neck, scalp and ears are treated (see below) the dosage may be increased to ensure total body coverage.

In women, the whole body application should include the breasts.

After application, clean clothes should be put on.

The whole body should be washed thoroughly 8-12 hours after treatment.

During the treatment period, Permetherin Dermal Cream should be re-applied to the hands if they are washed with soap and water.

Approximately 90% of individuals are cured with a single application of cream. If necessary, a second application may be given, not less than 14 days after the initial application, if there are no signs of the original lesions healing or if new lesions are present.

Paediatric population

Children should apply the cream uniformly to the whole body, including the palms of the hands, soles of the feet, neck, face, ears and scalp. Parts of the skin around the mouth (because the cream could be licked off) and the eyes should be spared. Children should be kept from licking the cream from the hands. If necessary, children should wear gloves.

Only limited experience is available in children aged 2 months to 23 months. Therefore, treatment must be given only under close medical supervision in this age group.

Elderly:

Elderly patients (over 65 years) should use the cream in the same way as adults, but in addition, the face, ears and scalp should also be treated. Care should be taken to avoid applying the cream to areas of skin around the eyes.

Treatment of Crab Lice

Posology

Use in adults and children over 2 months, and the elderly:

Children under 18 should seek medical advice before using the product.

Patients over 70 years should be treated under medical supervision.

It is recommended that up to one-third of a 30 g tube should be sufficient to treat the pubic region, peri-anal region, thighs and trunk. A few adults may need to use more cream to ensure a complete treatment, but not more than two-thirds of a tube should be used.

For children and relatively hair-free individuals proportionately less cream will be required.

The cream should be removed by washing at least 8 hours but not greater than 24 hours after being applied.

Sufficient cream should be applied to cover the pubic region, peri-anal area, inner thighs down to the knees and any hair on the trunk, which extends to the pubic area. Any facial hair, except the eyelashes and eyebrows should also be treated if found to be infested with lice or their eggs.

Since the dermal cream may cause marked eye irritation, it is recommended that any lice or eggs found in the eyelashes should be remove with a pair of tweezers. Permethrin Dermal Cream should not be applied to this area.

It is unusual for crab lice to infest the eyebrows. Lice or eggs found in this area are more likely to be head lice and therefore care should be exercised when making a diagnosis.

A second treatment should be administered if live lice are found on previously treated area 7 days after treatment.

Direct contacts may also need to be treated.

4.3 Contraindication

Hypersensitivity to the active substance permethrin, other substances of the pyrethrin group, any of the excipients listed in section 6.1, or to chrysanthemums. In such cases treatment should be switched to a chemically different antiscabies agent.

4.4 Special Warning and Precautions for use

In the case of hypersensitivity to chrysanthemums or other compositae, treatment should only be given if strictly indicated.

When using Permethrin Dermal Cream, care should be taken not to allow the cream to get into the eyes or come into contact with mucous membranes (e.g. nasopharyngeal space, genital area) or open wounds.

If skin irritation occurs and does not improve, patients should consult a doctor.

Paediatric population

Only limited experience is available with Permethrin Dermal Cream in children aged 2 months to 23 months. Therefore treatment must be given only under close medical supervision in this age group.

For cutaneous use only.

Permethrin Dermal Cream is for external use only and should be kept out of the sight and reach of children.

Permethrin is not an eye irritant, but contact of Lyclear Dermal Cream with the eyes should be avoided because other components of the product can cause marked irritation. In the event of inadvertent eye contamination, the affected area should be rinsed immediately with plenty of water or, if readily available, normal saline.

In the event of accidental ingestion of permethrin, please seek immediate medical attention.

It is important to ensure that the course of treatment is followed as directed because treatment failure has been reported when this has not occurred.

Nursing staff who routinely apply Permethrin Dermal Cream may wish to wear gloves to avoid any possible irritation to the hands.

Direct contacts should be treated. If no improvement occurs consult the doctor. Pyrethrins are used as an agricultural and horticultural insecticide, the potential for sensitisation through this route should be kept in mind.

Elderly patients

There is an increasing body of data specifically relating to the use of Permethrin Dermal Cream for the treatment of scabies in the elderly, and in view of these data it is considered that there is no need for any special precautions for use in this age group.

Excipients – Important Information

Note: The excipient of the cream, liquid paraffin, can reduce the functioning and hence the reliability of latex products (e.g. condoms, diaphragms) used at the same time.

Permethrin Dermal Cream contains formaldehyde which may cause local skin reactions (e.g. contact dermatitis).

Permethrin Dermal Cream contains butylhydroxytoluene (E321) which may cause local skin

reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

4.5 Interaction with Other Drugs, other forms of interactions:

No interactions are known.

The treatment of eczematous-like reactions with corticosteroids should be withheld prior to treatment with Permethrin Dermal Cream, as there is a risk of exacerbating the scabies infestation by reducing the immune response to the mite. The likelihood of interactions between the two treatments leading to potentiated adverse reactions or reduce efficacy is, however, considered small.

4.6 Fertility Pregnancy and Lactation:

Pregnancy

There are limited data on the use of Permethrin Dermal Cream in pregnancy which provide no indication of any risk to the foetus. Furthermore the amount of permethrin absorbed systemically following a whole body application is extremely low, less than 0.5% of the applied dose is absorbed. These data together with the negative mutagenicity tests and the very low mammalian toxicity would suggest that any risk to the foetus following treatment with Permethrin Dermal Cream is minimal. Women who are pregnant should use permethrin only after prior consultation with a healthcare professional.

Breast-feeding

Studies, following oral administration of permethrin in cattle have indicated that very low concentrations of permethrin are excreted in milk. It is not known whether permethrin is excreted in human breast milk, although there are very limited data, which suggest that suckling infants are unaffected following maternal use of permethrin containing products. However, because only extremely small amounts of permethrin are absorbed systemically following treatment with Permethrin Dermal Cream and in theory only a very small percentage of this systemic permethrin may pass into the breast milk, it is unlikely that the concentrations of permethrin in the milk will present any risk to the neonate/infant. Women who are breastfeeding should only use permethrin containing products after consultation with a healthcare professional.

4.7 Effects on ability to drive and use machine:

Permethrin is unlikely to have any effects on the ability to drive and use machines.

4.8 Undesirable Effects:

Adverse reactions are listed below by MedDRA system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports.

function, therefore caution should be exercised when treating elderly patients with emtricitabine*/tenofovir disoproxil.

System Organ class	**Common** (≥1/100 to <1/10)	**Rare** (≥1/10,000 to <1/1,000)	**Very rare** (<1/10,000)	**Not known** (cannot be estimated from the available data)
Nervous system disorders	Parasthesia, skin burning sensation			
Respiratory, thoracic and mediastinal disorders			Dyspnoea (in sensitive/allergic patients)	
Skin and subcutaneous tissue disorders	Pruritus, erythematous rash, dry skin		Excoriation, folliculitis, skin hypopigmentation	Urticaria

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 Overdoses:

On the basis of animal and human volunteer studies, it is unlikely, even with misuse or excessive topical application that the amount of permethrin required to produce clinically relevant toxic effects would be reached.

In the event of accidental ingestion of permethrin, please seek immediate medical attention.

Symptoms

Symptoms of overdose are generally likely to occur after accidental or deliberate oral ingestion due to swallowing and in rare cases because of skin absorption following excessive topical application and may include dizziness, loss of appetite, nausea, vomiting, headache, weakness, seizures, and loss of consciousness.

It is possible that excessive application of Permethrin Dermal Cream might result in localised adverse reactions as described in the side- and adverse effects section or more severe skin reactions.

Management

Symptomatic treatment is indicated should hypersensitivity-type reactions occur.

In the event of overdose or accidental ingestion of the contents of a tube of Permethrin Dermal Cream by a child, gastric lavage should be considered if consultation is within 2 hours of ingestion.

5. Pharmacological Properties:

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Pyrethrines, incl. synthetic compounds, ATC code: P03AC04

The principle physiological action in insects (lice) exposed to permethrin is induction of electrochemical abnormalities across the membranes of excitable cells, leading to sensory hyper excitability, in co-ordination and prostration. It is assumed that the mode of action against arachnids (mites) is similar.

Paediatric population

Newborns and infants: The safety and efficacy of permethrin in newborns and infants under 2 months of age have not been established since no data are available from prospective trials or larger case series. A limited number of case reports in the treatment of children under 2 months of age presenting with scabies do not suggest specific safety concerns for the use of topical permethrin in this age group, but no definite conclusion can be drawn.

5.2 Pharmacokinetic properties

Investigations with the 5 % cream in humans revealed an average percutaneous absorption rate of 0.47 ± 0.3 % in healthy subjects and of 0.52 ± 0.3 % in patients. Pharmacokinetic properties were studied in adult subjects only (6 healthy volunteers and 6 patients with scabies). Absorbed

permethrin is rapidly broken down by esterases as well as hydrolases. After oral administration, peak plasma concentrations are reached in approximately 4 hours. The isomeric mixture is then excreted in the urine in the form of glucuronides, sulfates etc as cis- trans CI2CA [(3- (2,2-dichlorovinyl)-2,2-dimethylcyclopropane-1-carboxylic acid)] and after oxidation to 3 PBA (3- phenoxybenzoic acid). After oral application, up to 6 % is excreted unchanged in the faeces whilst on dermal application, unchanged permethrin is virtually undetectable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazards for humans based on studies of acute and repeated dose toxicity, genotoxicity and carcinogenic potential. Effects in reproductive studies were only seen at exposures considered sufficiently in excess of the exposure expected for the topical use of a 5% cream. Environmental risk assessment studies have shown that permethrin may pose a risk for aquatic organisms (daphnia and fish) and terrestric organisms (plants) (see section 6.6).

6. Pharmaceutical Particulars:

6.1 List of Excipients:

Butylated Hydroxytoluene

Carbomers

Coconut Oil

Glycerol

Glycerol Monostearate

Liquid Paraffin

Sodium Hydroxide

Formaldehyde

Purified Water

6.2 Incompatibilities:

Not Applicable

6.3 Shelf – life:

36 Months

6.4 Special Precautions for Storage:

Do not store above 30˚C. Protect from light and heat.

Keep out of the reach of children.

6.5 Nature and Contents of Container:

Each 30 gm lami tube packed in a printed carton.

6.6 Special precautions for disposal and other handling

This medicinal product may pose a risk to the environment. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder:

KWALITY PHARMACEUTICAL LTD

Vill. Nag Kalan, Majitha Road, Amritsar-143601 India.

8. Marketing Authorization Number: NA

9. Date of First Authorization / Renewal of Authorization: NA

10. Date of Revision of the Text: NA