
PERMETHRIN CREAM 5.0% W/W

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)**1. Name of medicinal product**

Permethrin Cream 5.0% w/w

2. Composition:

Permethrin BP 5% w/w

Cream base q.s.

3. Pharmaceutical Form:

Topical

4. Clinical Particulars**4.1 Indication**

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

4.2 Posology and Administration

Permethrin 5% w/w Cream is suitable for adults, children of 2 months of age and above, and the elderly.

Permethrin 5% w/w Cream is for external use only and should not be applied to broken skin, mucous membranes or near the eyes.

Permethrin 5% w/w Cream should be applied to skin which is clean dry and cool. It should not be used immediately after a hot bath.

Permethrin 5% w/w 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.

Reapply the cream to the hands if they are washed within 8 hours of treatment.

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

4.3 Contraindication

Hypersensitivity to the active substance(s) or to any of the excipients.

4.4 Special Warning & precautions for use

Permethrin 5% w/w Cream should be kept out of the sight and reach of children.

Permethrin 5% w/w Cream is for external use only. Nursing staff who routinely apply Permethrin 5% w/w Cream may wish to wear gloves to avoid any possible irritation to the hands.

Carers who apply permethrin are advised to wear gloves.

Permethrin is not an eye irritant but contact of Permethrin 5% w/w Cream with the eyes should be avoided because the cream itself may 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.

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In the case of hypersensitivity to chrysanthemums or other compositae, treatment should only be given if strictly indicated. In such cases treatment should be switched to achemically different agent.

There is an increasing body of data specifically relating to the use of Permethrin 5% w/w 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.

Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies found.

4.6 Fertility, Pregnancy and lactation

Permethrin Cream should only be used in pregnancy when the potential benefits outweigh the possible risks of treatment.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

In scabies patients, skin discomfort (paraesthesias), usually described as burning, stinging or tingling, occurs in a few individuals soon after Permethrin 5% w/w Cream is applied.

4.9 Overdose

Application of a full tube (30 g) of cream to a 2-month old would result in a dose of approximately 350 mg/kg bodyweight. Even if 100% of the permethrin absorbed, this dose would be unlikely to cause overt signs of systemic toxicity.

It is possible that excessive application of Permethrin 5% w/w Cream to the skin might result in localised adverse reactions or more severe skin reactions. Treatment of hypersensitivity-type reactions should be symptomatic.

Symptoms of overdose may include nausea, headache, vomiting, dizziness and convulsion.

In the event of accidental ingestion of the contents of a tube of Permethrin 5% w/w Cream by a child, gastric lavage should be considered if consultation is within 2 hours of ingestion.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

Permethrin is rapidly metabolised in mammals by ester hydrolysis to inactive metabolites which are excreted principally in the urine. The principal metabolites of permethrin are detectable in the urine within 7 hours of whole body application of the cream to healthy volunteers or scabies patients. The highest levels of excretion are detectable within 48 hours but very low levels of metabolite are still detectable in the urine of some individuals 28 days after treatment. The overall pattern of excretion indicates a mean of approximately 0.5% of applied permethrin is absorbed during the first 48 hours.

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6. Shelf Life

36 months

7. Special precaution for Storage

Do not store above 30°C.

8. Nature and contents of container

30 gm tube packed in carton along with insert.

9. Marketing Holder

YOGI CARE PHARMACEUTICAL PRIVATE LIMITED

OFFICE-1113,1114, BINORI B SQUARE - 3, SINDHU BHAVAN
ROAD, NR. TRADE BULLS, Bodakdev, Ahmedabad, Ahmedabad,
Gujarat, 380054

10. Manufacturer

SPENSUS PHARMACEUTICALS PRIVATE LIMITED

Unit No. 1, survey No. 284, Ganeshpura, Gujarat - 382705