

Permisol[®]

Presentation:

Permisol[®] cream: White, smooth cream containing permethrin INN 5% w/w.

Uses: **Permisol[®]** cream is indicated for the treatment of scabies and crab lice infestations.

Dosage and administration:

In view of the great individual variability in body surface area and skin type, precise recommendations are not possible.

The following table indicates the approximate amount of cream to be used as single application:

Adults and children	over 12 years	: Up to 1 tube
Children	6-12 years	: Up to ½ of a tube
	1-5 years	: Up to ¼ of a tube
	2 months-1 year	: Up to 1/8 of a tube

A few adults may need more than one tube (30gm of cream) for whole body application, however the maximum amount of **Permisol[®]** cream used in one application should be limited up to two tubes (60gm of cream)

Ensure that the skin is clean, dry and cool prior to treatment.

Contraindications, warnings, etc.

Contraindications : It is contraindicated in individuals with a known allergy to Permethrin, its components, other pyrethroids or pyrethrins.

Precautions and warnings : For external use only. Avoid contact of **Permisol[®]** cream with eyes. In the event of inadvertent eye contamination, rinse with water, or normal saline if possible. When applying **Permisol[®]** cream in the face of the children, care should be taken when applying to areas close to the eyes and mouth, where it may be licked off. Nursing staff who routinely come in contact with the cream may wear gloves to avoid any possible irritation to the hands.

Side effects: Skin discomfort, usually described as burning or stinging occurs in a few individuals soon after **Permisol[®]** cream is applied. This symptom occurs more frequently in patients with severe scabies and is usually mild and transient. Other signs and symptoms of irritation, including erythema, oedema, eczema, rash and pruritus are considered to be part of the natural history of scabies. In some treated patients, itching may persist because of allergic reactions to the dead mites under the skin and does not necessarily signify a treatment failure.

Mutagenicity/ Carcinogenicity/ teratogenicity: Permethrin does not have the potential to induce mutagenic changes.

Permethrin has no significant oncogenic potential in humans.

No evidence of teratogenicity has been found in mice, rats, or rabbits.

Pregnancy and lactation:

There is limited data on the use of **Permisol**[®] cream in pregnancy, however, there is no indication of any risk to the foetus. The amount of Permethrin absorbed is extremely low, less than 0.5%. Any risk to the foetus following treatment with **Permisol**[®] is minimal. It is not known whether Permethrin is excreted in human breast milk. As extremely small amounts are absorbed, it is unlikely, to present any risk to the neonate/infant.

Drug interactions:

There are no known drug interactions with permethrin.

Treatment with corticosteroids in eczematous conditions should be withheld, as there is the risk of exacerbating the scabies infestation by reducing the immune response to the mite.

Toxicity and treatment of over dosage:

No instance of over dosage or **Permisol**[®] cream has been reported.

Application of a full tube of cream to a 2 month-old-child would result in a dose of approximately 350mg/kg body weight to the skin. It is unlikely that such a dose would cause overt signs of toxicity even if 100% of the Permethrin was absorbed. It is likely that massive over dosage of Permethrin would result in localized adverse reactions described above.

Treatment of over dosage:

Symptomatic prescription is indicated. In case of accidental ingestion by a child, gastric lavage should be done within 2 hours of ingestion.

Directions for use:

Treatment procedures for adults (excluding the elderly and the children over 2 years):

Apply **Permisol**[®] cream over the whole body, excluding the head, paying particular attention to the areas between the fingers and toes, wrists, axillae, external genitalia and buttocks. The whole body should be washed thoroughly 8-12 hours later. If any area of the body is subsequently washed with soap and water during the treatment period, **Permisol**[®] cream should be reapplied.

Nature of the cream is such that it disappears when rubbed gently into the skin. It is, therefore not necessary to apply the cream until it remains detectable on the majority of individuals, scabies infection is cleared with a single application. If necessary, however, **Permisol**[®] cream may be reapplied after seven days of initial application.

Use in the elderly and children between 2 months to 2 years of age:

Prescription procedure for these patient groups is the same as directed for adults and children above 2 years. However, as scabies lesions on the face, neck, scalp, and ears are more widespread in these patients, **Permisol**[®] cream should also be applied to these areas, where affected. Avoid areas close to the eyes.

Pharmaceutical precautions :

Store in a cool & dry place. Protect from light.

Package quantities :

Permisol[®] cream: Tube of 15g & 30g

® Registered Trade Mark



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