

# AROTRIX<sup>®</sup> Cream

Permethrin INN 5%

## Composition:

Each gram cream contains Permethrin INN 50 mg.

## Indications:

**AROTRIX<sup>®</sup>** Cream is indicated for the treatment of scabies and lice infestations.

## Dosage and administrations:

Precise recommendations for administration of **AROTRIX<sup>®</sup>** Cream are not possible because of variation in body surface and skin type from patient to patient. However, the approximate amount of cream to be used is given as follows:

Adults & children over 12 years	: Up to 30 g cream
Children of 6-12 years	: Up to 15 g cream
Children of 1-5 years	: Up to 7.5 g cream
Children of 2 months-1 year	: Up to 3.75 g cream

A few adults may need to use an additional tube (30 g) for full body coverage but should not use more than 2 tubes (60 g in total) at each application. Before use, ensure that your skin is clean, dry and cool.

## Directions for application for adults & children over 2 years:

Apply **AROTRIX<sup>®</sup>** Cream in the skin over the whole body, excluding the head & face, taking particular attention to the areas between the fingers & toes, wrists, axillae, external genitalia, breasts 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, **AROTRIX<sup>®</sup>** Cream should be reapplied.

**Children under 2 years:** Directions for application for such patients are the same as directed for adults and children over 2 years. An adult must supervise a children for the treatment with **AROTRIX<sup>®</sup>** Cream.

## Contra-indications:

Permethrin is contraindicated in subjects with known hypersensitivity to product, its components, other pyrethroids or pyrethrins.

## Warning and Precaution:

For external use only. Avoid contact of **AROTRIX<sup>®</sup>** Cream with the eyes. In the event of inadvertent eye contamination, rinse with water, or normal saline if possible. Care should be taken when applying **AROTRIX<sup>®</sup>** Cream to the face of children especially to the areas close to the eyes and mouth, where it may be licked off. Nursing staff who routinely come in contact with the cream wear gloves to avoid any possible irritation to the hands.

## Side effects:

Burning or stinging occurs in a few patients soon after application of **AROTRIX<sup>®</sup>** Cream. This symptom occurs more frequently in patients with severe scabies and is usually mild and transient. Other signs and symptoms include erythema, oedema, eczema, rash which are considered to be part of the natural history of scabies.

## Use in pregnancy and Lactation:

There is limited data on the use of **AROTRIX<sup>®</sup>** Cream in pregnancy. However, there is no indication of any risk to the fetus. The amount of Permethrin absorbed is extremely low. It is not known whether Permethrin is excreted in human breast milk or not. As extremely small amounts are absorbed, it is unlikely to present any risk to the neonate/infant.

## Drug Interactions:

There is no known drug interaction with Permethrin. Treatment with corticosteroids in eczematous condition should be held, as there is the risk of exacerbating the scabies infestation by reducing the immune response to the mite.

## Storage:

- Store below 30<sup>0</sup> C, protect from light and keep in a dry place.
- Keep out of the reach of children.

## Packing:

**AROTRIX<sup>®</sup>** Cream: Each tube containing 15 g/30 g cream.