

Arotrix-C

Permethrin BP 5% & Crotamiton BP 10%

COMPOSITION

Arotrix-C Lotion: Each ml lotion contains Permethrin BP 50 mg and Crotamiton BP 100 mg with fragrance.

PHARMACOLOGY

Permethrin is a synthetic pyrethroid; scabicide and pediculicide. It acts on the sodium channels of parasite nerve membranes, causing prolonged depolarization, paralysis, and eventual death of the ectoparasite (e.g., *Sarcoptes scabiei* in scabies). When applied topically, the absorption is less than 0.5% during the first 48 hours. Absorbed Permethrin is rapidly metabolized in the liver by ester hydrolysis to inactive metabolites which are excreted primarily in the urine. Crotamiton is a scabicide and antipruritic. The exact mechanism is unclear; but it has anti-itch and anti-parasitic effects which reduce inflammation by disrupting the cellular processes of mites. It shows limited systemic absorption and acts locally on the skin.

INDICATION

Arotrix-C Lotion is indicated for the treatment of scabies and pruritus. Moreover, it is used for the relief of itching and skin irritation like sunburn, dry eczema, itchy dermatitis, allergic rashes, hives, nettle rash, chickenpox, insect bite and stings, heat rashes and personal itching.

DOSAGE & ADMINISTRATION

Arotrix-C Lotion is suitable for adults, children of 2 months of age and above, and the elderly. It is for external use only and should not be applied to broken skin, mucous membranes or near the eyes. **Arotrix-C Lotion** should be applied to skin, which is clean, dry and cool. It should not be used immediately after a hot bath.

Arotrix-C Lotion is intended for a single application over the whole body from the neck down to the soles of the feet, especially in body folds, after bathing when the skin is dry and clean. After 8-12 hours of application, the entire body should be thoroughly washed, and worn clothes and bed sheets should be washed with hot water. As a preventive measure, other family members should also use the lotion.

Adults, Children over 2 years & Elderly: For children over 2 years & adults apply the lotion over the whole body but not the head and face. For the elderly patient apply the lotion over the whole body including the neck, face, ears and scalp. For all pay particular attention to the areas between fingers and toes, under nails, wrists, armpits, external genitalia, breasts and buttocks. Avoid the area close to the eyes.

Children under 2 years: Children under 2 years should only be treated under medical supervision. Apply the lotion over the whole body including the neck, face, ears and scalp. Pay particular attention to the areas between fingers and toes, under nails, wrists, armpits, palms of hands and soles of feet, external genitals and buttocks. Avoid the area around the mouth where the lotion could be licked off and the area around the eyes.

Shake the bottle well before use.

CONTRAINDICATION

Combination of Permethrin and Crotamiton is contra-indicated in patients with known hypersensitivity to permethrin or crotamiton.

WARNING & PRECAUTION

Combination of Permethrin BP 5% and Crotamiton BP 10% lotion should be kept out of the reach of children. This lotion is for external use only. Nursing staff who routinely apply the lotion may wish to wear gloves to avoid any possible irritation to the hand. Avoid contact with the eyes. If the lotion comes into contact with the face or eyes, it should be rinsed off immediately with water. If excessive burning or irritation occurs, discontinue using and consult a physician if necessary.

SIDE EFFECTS

Occasional reports of burning or stinging sensation which passes quickly. This is usually mild and occurs more frequently in patients with severe scabies. Transient signs and symptoms of skin irritation including rash or itching, erythema, oedema and eczema. These are generally considered to be part of the natural history of scabies.

USE IN PREGNANCY & LACTATION

There is no experience to judge the safety of Permethrin & Crotamiton in pregnancy, therefore it is not recommended during pregnancy, especially in the first three months. It is not known whether the active substance passes into breast milk. Nursing mothers should avoid applying it around the nipples.

DRUG INTERACTION

The treatment of eczematous-like reactions with corticosteroids should be withheld prior to treatment with permethrin, 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 potential adverse reactions or reduced efficacy is, however, small.

OVERDOSE

There are no reports of over dosage of Permethrin & Crotamiton. Excessive application to the skin might result in adverse local reactions. In the event of accidental ingestion by a child, gastric lavage should be considered within 2 hours of ingestion. The treatment of hypersensitivity reactions should be symptomatic.

STORAGE

- Store below 30°C temperature & dry place, protect from light.

- Keep out of the reach of children.

PACKING

Arotrix-C Lotion: Each bottle contains 60 ml lotion.

Manufactured by:

 ARISTOPHARMA LTD.

Shampur-Kadamtali I/A, Dhaka-Bangladesh

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