

# METHRIX<sup>Lotion</sup>

(Permethrin)

## COMPOSITION:

Each gram contains:

Permethrin .....50mg

(Innovator's Specifications.)

## DESCRIPTION:

Permethrin is a pyrethroid insecticide commonly used in the treatment of lice infestations and scabies. It is a yellow to light orange-brown, low melting solid or viscous liquid. It is used to prevent infestation with *Sarcoptes scabiei* (scabies).

## MECHANISM OF ACTION:

Permethrin acts on the nerve cell membrane to disrupt the sodium channel current by which the polarization of the membrane is regulated. Delayed repolarization and paralysis of the pests are the consequences of this disturbance.

## INDICATIONS:

Permethrin Lotion is indicated for the treatment of scabies.

## DOSAGE & ADMINISTRATION:

### Adults, elderly and children over 2 years of age:

Permethrin Lotion 5% w/w should be shaken before use. Prior to application, the skin should be clean, dry and cool. A hot bath should not be taken prior to treatment. The lotion should be thoroughly massaged into the skin from the neck to the soles of the feet, paying particular attention to the areas between the fingers and toes, under the fingernails and toenails, wrists, armpits and genital area and buttocks. Permethrin Lotion 5% w/w disappears when rubbed gently into the skin; it is, therefore, not necessary for the patient to apply the medication until the lotion remains detectable on the skin. If the hands are washed with soap and water during the treatment period, Permethrin Lotion 5% w/w should be reapplied. The following table indicates how much lotion would normally be used:

### Adults and children over 12 years:

Up to one 50ml bottle

### Children:

5 to 12 years: Up to half of one 50ml bottle

1 to 5 years: Up to a quarter of one 50ml bottle

2 months to 1 year: Up to an eighth of one 50ml bottle

The patient should put on clean clothes and leave the lotion in place for 12 to 14 hours. The lotion should then be washed off thoroughly during a shower or a bath. Patients should again change into clean clothes. One treatment is usually adequate to eliminate the scabies. However, if live mites are present, or new skin lesions

میتھرکس لوشن  
(پریمتھرین)

appear, a second application can be given seven to ten days later.

### Children 2 months to 2 years of age:

Prior to application, the skin should be clean, dry and cool. A hot bath should not be taken prior to treatment. The lotion should be thoroughly massaged into the child's whole body, including their neck, face, ears and scalp. The area around the mouth and eyes should be avoided. The child should put on clean clothes and leave the lotion in place for 12 to 14 hours. The lotion should then be washed off thoroughly during a shower or a bath. The child should be dressed in clean clothes. One treatment is usually adequate to eliminate the scabies. However, if live mites are present, or new skin lesions appear, a second application can be given seven to ten days later. The safety and efficacy of Permethrin Lotion 5% w/w in children under 2 months of age have not been established. No data are available.

## PHARMACOKINETICS:

Permethrin is rapidly metabolised by ester hydrolysis to inactive metabolites which are excreted primarily in the urine. The application of cream rinse to the hair of volunteers for the recommended application time resulted in extremely low or undetectable levels of permethrin metabolites in plasma and urine samples. In vitro studies have shown that permethrin levels on hair were not affected by chlorine in concentrations used in swimming pools.

## WARNINGS & PRECAUTION:

Keep out of the sight and reach of children. For external use only. Gloves may be worn to avoid possible irritation to the hands of nursing staff who routinely use Permethrin Lotion 5% w/w.

Avoid contact with eyes. Permethrin is not an eye irritant but eye contact with Permethrin Lotion 5% w/w should be avoided because the lotion itself may cause irritation. In case of contact, rinse immediately with water. If a reaction occurs, discontinue use and consult your doctor. Only limited experience is available with Permethrin Lotion 5% w/w in children aged 2 months to 23 months. Therefore treatment must be given only under close medical supervision in this age group.

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 a chemically different agent.

## Pregnancy and lactation

There is inadequate evidence of the safety in human pregnancy. Permethrin Lotion 5% w/w should only be

used when the expected benefits outweigh the potential risks. Nevertheless, the amount of permethrin absorbed systemically following a whole body application is extremely low while the negative mutagenicity tests and the very low mammalian toxicity would suggest that any risk to the foetus following treatment with Permethrin Lotion 5% w/w is minimal.

There is no evidence of teratogenicity in reproduction studies in mice, rats and rabbits.

It is not known if permethrin is excreted in human milk, although it is unlikely that concentrations would present any risk to the infant. It is recommended that nursing be discontinued or treatment withheld if it is not possible to discontinue nursing. However, because only very small amounts of permethrin are absorbed systemically following treatment with Permethrin Lotion 5% w/w, it is unlikely that the concentration of permethrin in the milk will present any risk to the neonate/infant.

## SIDE EFFECTS:

### Nervous system disorders:

Paraesthesia

### Skin and subcutaneous tissue disorders:

Localised reactions and erythema have been infrequently reported with topical use of permethrin, but they are usually mild and resolve rapidly after cessation of treatment.

In scabies patients, skin discomfort, usually described as burning, stinging or tingling, occurs in a few people soon after Permethrin Lotion 5% w/w is applied. This occurs more frequently in patients with severe scabies and is usually mild and transient.

Other transient signs and symptoms of irritation, including edema eczema and rash may occur, together with itching which may be temporarily exacerbated or may persist for several weeks after treatment, but does not indicate a treatment failure. Retreatment is only necessary if live mites appear or new lesions develop.

## DRUG INTERACTIONS:

None have been reported.

The treatment of eczematous-like reactions with corticosteroids should be withheld prior to treatment with, Permethrin Lotion 5% w/w as there is a risk of exacerbating the scabies infestation by reducing the immune response to the mite. However, the likelihood of interactions between the two treatments leading to potential adverse reactions or reduced efficacy is small.

## CONTRAINDICATIONS:

The use of Permethrin Lotion 5% w/w is contraindicated in people with hypersensitivity to permethrin, any synthetic pyrethroid or pyrethrin, or to chrysanthemums.

## STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight and moisture. Keep away from the reach of the children. **Shake well before use.**

To be sold on the prescription of a registered medical practitioner only.

FOR EXTERNAL USE ONLY.

HOW SUPPLIED:

Methrix Lotion: 60ml

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ دھوپ گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے کے مطابق فروخت کریں۔ استعمال سے پہلے اچھی طرح ہلائیں۔

Manufactured by:

**PHARMA SOL**

**PRIVATE LIMITED**

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Lahore, Pakistan.