# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. Name of the medicinal product

**BRUTHRIN CREAM** (Permethrin Cream 5% w/w)

## 2. Qualitative and quantitative composition

Contains:

| | |
|---|---|
| Permethrin BP | 5% w/w |
| In Cream Base | q.s. |

## 3. Pharmaceutical form

Cream

## 4. Clinical particulars

### 4.1 Therapeutic indications

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

### 4.2 Posology and method of 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.

Children under 2 years should only be treated under medical supervision.

Older children should be supervised when applying the cream to ensure that a thorough treatment is administered.

In view of the great variability in body area and skin types, precise dosage recommendations are not possible.

In cases where the head, neck, scalp and ears are treated (see below), the dosage may be increased to ensure total body coverage.

| | |
|---|---|
| Adults, the elderly & children over 12 years | Normally, up to one tube (30g). A few adults may need to use an additional tube for full body coverage but should not use more than 2 tubes (60g in total) at each application. |
| Children 6 to 12 years | Up to half a tube (15g). |
| Children 1 to 5 years | Up to a quarter of a tube (7.5g). |
| Children 2 months to 1 year | Up to an eighth of a tube (3.75g). |

*Adults & children over 2 years:*

Apply the cream over the whole body but NOT the head and face. Pay particular attention to the areas between fingers and toes, under nails, wrists, armpits, external genitalia, breasts and buttocks.

*The elderly:*

Apply the cream 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, external genitalia, breasts and buttocks. Avoid the area close to the eyes.

*Children under 2 years:*

Apply the cream 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 cream could be licked off and the area around the eyes.

Approximately 90% of individuals are cured after a single application. If there are no signs of the original lesions healing or if new lesions have appeared, a second application can be made not less than 7 days after the first application.

**4.3 Contraindications**

Permethrin 5% w/w Cream is contra-indicated in subjects with known hypersensitivity to the product, its components, other pyrethroids or pyrethrins.

**4.4 Special warnings and precautions for use**

Permethrin 5% w/w Cream should be kept out of the 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.

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.

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.

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.

**Paediatric population**

Only limited experience is available with Permethrin 5% w/w Cream in children aged 2 months to 23 months. Therefore treatment must be given only under close medical supervision in this age group.

**4.5 Interaction with other medicinal products and other forms of interaction**

No interactions are known.

The treatment of eczematous-like reactions with corticosteroids should be withheld prior to treatment with Permethrin 5% w/w Cream, 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 potentiated adverse reactions or reduced efficacy is, however small.

**4.6 Pregnancy and lactation**

The limited data available on the use of Permethrin 5% w/w Cream in pregnancy which provide no indication of any risk to the foetus. The amount of permethrin absorbed systemically following a whole body application is extremely low. However, some permethrin may pass the placental barrier. The negative mutagenicity tests and the very low mammalian toxicity suggest that there is minimal risk to the foetus following treatment with permethrin.

It has been shown that very low concentrations of permethrin are excreted in milk following oral administration of permethrin in cattle. It is not known whether permethrin is excreted in human breast milk. However, because only extremely small amounts of permethrin are absorbed systemically and in theory only a very small percentage of this will pass into the breast milk, it is unlikely that the concentrations of permethrin in the milk will present any risk to the neonate/infant.

Reproduction studies in mice, rats and rabbits given oral dosage of 200 to 400 mg/kg bodyweight/day revealed no evidence of impaired fertility. In addition permethrin did not show any adverse effects on the reproductive function of rats given an oral dosage of 180 mg/kg bodyweight/day in a three generation study.

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

**4.7 Effects on ability to drive and use machines**

None 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. This occurs more frequently in patients with severe scabies and is usually mild and transient.

Other transient signs and symptoms of irritation, including erythema, oedema, eczema, rash and pruritus which may follow treatment of scabies with Permethrin 5% w/w Cream are generally considered to be part of the natural history of scabies.

In patients treated for scabies, itching may persist for up to 4 weeks post-treatment. This is generally regarded as due to an allergic reaction to the dead mites under the skin and is not necessarily indicative of a treatment failure.

**4.9 Overdose**

There are no reports of overdosage of Permethrin 5% w/w Cream.

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.

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 principal physiological action in susceptible parasites exposed to permethrin is induction of electrochemical abnormalities across the membranes of excitable cells, leading to sensory hyper-excitability, inco-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.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

| Sr No. | Ingredients |
|---|---|
| 1. | Macrogol (PEG-400) |
| 2. | Cetomacrogol-1000 |
| 3. | Cetostearyl Alcohol |
| 4. | Light Liquid Paraffin |
| 5. | White soft Paraffin |
| 6. | Purified Water |

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

30 Months

**6.4 Special precautions for storage**

Store at temperature not exceeding 30ºC. Do not Freeze.

**6.5 Nature and contents of container**

30g Lami tube packed in unit carton along with package insert.

**6.6 Special precautions for disposal and other handling**

None.

**7. Marketing authorisation holder**

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**8. Marketing authorisation number(s)**

05571/08125/NMR/2020

**9. Date of first authorisation/renewal of the authorisation**

Dec 17, 2020

**10. Date of revision of the text**

Dec 17, 2020