

TECHNICAL DATA SHEET

1431-TDS-ENG-2026

PERMETRINA 25:75 (EUR. PH.) Farma		
DESCRIPTION DCI: permethrin		DESCRIPTION DOE: PERMETRINA
CAS N°: 52645-53-1	EC N°: 258-067-9	AEMPS CODE: 2647A
MOL. WEIGHT: 391,28	MOL. FORMULA: C ₂₁ H ₂₀ Cl ₂ O ₃	ARTICLE CODE: 1431

<u>ATTRIBUTES</u>	<u>SHOULD BE</u>
Appearance	Colourless or slightly brownish viscous liquid, semi-solid or crystalline solid
Solubility	Practically insoluble in water, very soluble in heptane, freely soluble in anhydrous ethanol, sparingly soluble in ethylene glycol
Identification A	Complies
Identification B	Complies
Related substances	
Impurity B	=< 0.15 %
Impurity C	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.50 %
Water	=< 0.25 %
Sulfated ash	=< 0.1 %
Assay	
Total	98.0 - 102.0 %
cis Isomer	23.0 - 27.0 %
trans Isomer	73.0 - 77.0 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

Keep the container tightly closed. Store it in a dry and well-ventilated place.

REMARKS

Permethrin 25:75 is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.

Properties and uses

PERMETHRIN is an insecticide and antiparasitic pyrethroid type, which acts on the nerve cells of insects causing rapid paralysis and death of them. It is the treatment of choice for infestations by *Sarcoptes scabiei* (mange), and *Pediculus humanus*, *Pediculus capitis*, and *Pediculus pubis* (lice). With just one application, it kills both the lice and their nits. It is used

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in children older than 2 years, applying after washing the head with a shampoo and when the hair is already dry. It is also used in the Demodex folliculorum infestation of the eyes or the one that accompanies acne rosacea. It is also active against ticks, mites, fleas, mosquitoes, black flies in their stages of larva or adult, and against the tsetse fly.

Dosage

In the treatment of capillary pediculosis or as an insect repellent, it is used in 1% lotion or shampoo. The lotion is applied only once and if it persists the infestation is repeated a week. The shampoo is applied for 4 days and repeated once a week. As acaricide (scabicide) is used in 5% cream or ointment only once, and cream is removed by washing the area at 8-14 h. As a spray insect repellent at 0.5% spraying clothes in the prevention of tick bites, or at 2.5% impregnating tissues and mosquito nets for the prevention of mosquito bites in the prophylaxis of malaria. In the infestation by Demodex folliculorum of the eyes, in gel at 1-5%, which is applied on the edges of the eyelids with a cotton swab once a week.

Side effects

Despite its low toxicity, can cause allergies, so you should avoid contact with mucous membranes, in which case should be washed immediately. May cause temporary increase in pruritus, edema and erythema, which accompanies the infestation, as well as producing contact dermatitis and allergic dermatitis.

Contraindications

Do not use in pregnancy and lactation.

Other observations

This product can FREEZE. If so, before use, heat it in a water bath (maximum 40°C) without the stopper and with all the necessary safety precautions.

Compounding examples*PERMETHRIN solution 5 %***PERMETHRIN - 5 %**Propylene glycol - **5 %**Hydroalcoholic solution 70% c.s.p. - **100 mL**

Modus operandi: Dissolve the pure PERMETHRIN (or the oil solution of PERMETHRIN activated at 25%) in 70% ethyl alcohol 96°, add 5% propylene glycol, and finally add the water.

*Suspension of PERMETHRIN 25 %***PERMETHRIN - 25 %**Tween 20 - **25 %**Ethanol 96% c.s.p. - **100 mL**

Modus operandi: Put the alcohol in a glass and add the PERMETHRIN and Tween 20, stirring on a magnetic stirrer at high speed for 2 min. Depending on the origin of the PERMETHRIN, a solution or a liquid-liquid suspension will be obtained. In the latter case, you will have to shake the product before using it.

*PERMETHRIN shampoo***PERMETHRIN - 5 %**Sulfonated anionic detergent c.s.p. - **100 g**

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Lotion of PERMETHRIN PERMETHRIN - **5 %**

Base lotion c.s.p. - **100 g**

Modus operandi: Dissolve the PERMETHRIN with alcohol 96° in mortar to form a paste and then add the lotion, made for example with Neo PCL O / W, glycerin 5%, and purified water.

Cream of PERMETHRIN for scabies

PERMETHRIN - **5 %**

Base cream Lanette c.s.p. - **30 g**

Modus operandi: When making the base cream, the PERMETHRIN is incorporated in the fat phase, or once the cream is prepared, the PERMETHRIN can be incorporated, homogenizing well with a rod.