

SUMMARY PRODUCT CHARACTERISTIC (SPC)

ANTILICE SHAMPOO FOR EXTERNAL USE

TRADE NAME – Antilice

INTERNATIONAL NON-PROPERTY NAME – Pyrethrins (permethrin+tetramethrin) + Piperonyl butoxide

DOSAGE FORM
Shampoo for external use.

COMPOSITION
Each ml of Antilice shampoo contains:
active ingredients: pyrethrins (permethrin + tetramethrin) - 1.65 mg, piperonyl butoxide – 16.5 mg;
inactive ingredients: cocamidopropyl betaine, polyquaternium, sodium lauryl sulfate, cocamide DEA, sodium chloride, disodium EDTA, methylparaben, citric acid, aroma apple, color «apple green» (E 142), water purified.

PHARMACOLOGICAL GROUP AND ATC CODE
Pediculicide; P03AC54.

PHARMACOLOGY
Antilice shampoo is a pediculicide combination. Following absorption through the chitinous exoskeleton of arthropods, pyrethrins stimulate the nervous system, apparently by competitively interfering with cationic conductances in the lipid layer of nerve cells, thereby blocking nerve impulse transmissions. Paralysis and death follow.
Piperonyl butoxide has little or no insecticidal activity but potentates that of pyrethrins by inhibiting the hydrolytic enzymes responsible for pyrethrin's metabolism in arthropods. When piperonyl butoxide is combined with pyrethrins, the insecticidal activity of the latter drug is increased 2-12 times.

Spectrum and Resistance

Pyrethrins are toxic to the parasitic arthropods *Pediculus capitis* (head louse), *Pediculus corporis* (body louse), and *Phthirus pubis* (crab louse), and possibly their nits. Resistance to pyrethrins may develop rarely in strains of *Pediculus corporis*. Some lice resistant to chlorophenothane (DDT) have been reported to be cross-resistant to pyrethrins. Pyrethrins are also toxic to house-flies, fleas, chiggers, and mosquitoes.

PHARMACOKINETICS
Pyrethrins are absorbed through intact skin when applied topically. Piperonyl butoxide reportedly is poorly absorbed through intact skin when applied topically. After 24 h after treatment, the concentration of its components in the blood plasma is minimal, and in some cases is not determined. After 48 h after applying Antilice no traces of its components in the patient's blood plasma is detected. In acute poisoning pyrethrins are inactivated in the digestive tract, and piperonyl butoxide is excreted unchanged in the feces.

USES AND ADMINISTRATION
Antilice is used for pediculosis capitis
Administration
Antilice shampoo is applied topically.

For the treatment of pediculosis capitis, enough shampoo of **Antilice** should be applied to cover the affected hairy and adjacent areas, taking care to avoid contact with the face (eyes, eyelashers, or mucous membranes). After 10 minutes, the hair is then washed thoroughly with water, dried with a clean towel, and combed with a fine tooth comb to remove any remaining nit shells.

Although the first treatment with **Antilice** is often successful, treatment should be repeated after 7-10 days to kill any newly hatched lice.

ADVERSE EFFECTS

Local reactions: burning, tingling, numbness, swelling, skin rash hairy parts of the body.

CONTRAINDICATIONS

- Hypersensitivity to components of drug.
- Childrens up to 2 years of age.

PREGNANCY AND LACTATION

Antilice is contraindicated during pregnancy and lactation.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The drug does not affect the ability to drive vehicles and operate machinery.

CAUTIONS

Contact with the face, eyes, mucous membranes, should be avoided. If accidental contact with the eyes occurs, the eyes should be flushed thoroughly with water, **Antilice** shampoo should not be applied to acutely inflamed skin or raw, weeping surfaces.

If primary irritation or hypersensitivity occurs in patients using **Antilice** shampoo, treatment should be discontinued, the drug washed off, and a physician consulted.

Containers of **Antilice** shampoo should be shaken before using.

The drug should not be applied more than once a day. Treatment of patients identified in one outbreak, as well as contact persons should be carried out simultaneously in order to avoid re-infection. All linen must be subjected to thorough processing. Bedding, towels, underwear should be boiled in a solution of detergent for 5-10 min. Outerwear irones on both sides with a hot iron.

Things that can not be heat treated, should be hung out outdoors for 3 days.

Information about Methylparaben

Antilice contains methylparaben, which may cause allergic reactions (possibly delayed).

OVERDOSE

Due to the low absorption into the systemic circulation overdose is unlikely.

DRUG INTERACTIONS

There are no interactions.

IDENTIFICATION

A greenish viscous liquid with an apple odor.

PRESENTATION

90 ml Shampoo for external use in plastic bottle inserted with the leaflet into cardboard box.

EXPIRY DATE

3 years. Do not use after the expiration date.

PRESCRIPTION STATUS

Without prescription.

STORAGE CONDITIONS

Store in a temperature not higher than 15°C, out of the reach of children. Protect from light.

MARKETING AUTHORIZATION HOLDER

“ARPIMED” LLC

Kotayk Marz, Abovyan, 2204, 2nd Micro-District, 19 Building, Republic of Armenia

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For any information about the medicine , please contact your local representative of the Marketing Authorization Holder.

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