

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Numark Head Lice Treatment 1% w/w Cutaneous Emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Permethrin 1% w/w

Excipients: Contains Cetostearyl Alcohol 3% w/w and Propylene Glycol (E 1520) 3% w/w.

‘For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Emulsion.

Numark Head Lice Treatment 1% w/w Cutaneous Emulsion is a smooth white liquid preparation for cutaneous application.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Numark Head Lice Treatment 1% w/w Cutaneous Emulsion is intended for the treatment of head lice (*pediculus humanus capitis*) infestations.

4.2 Posology & Method of Administration:

Numark Head Lice Treatment 1% w/w Cutaneous Emulsion is applied topically and is for external use only.

Adults and children over 3 years:

The lotion should be used after the hair has been washed with a mild non-conditioning and non-medicated shampoo and then towel dried. The bottle should be shaken thoroughly and the hair and scalp should be saturated with the lotion, with particular attention given to the areas at the back of the neck and behind the ears.

The lotion should be left on for 10 minutes. Thereafter, the hair should be rinsed thoroughly with water and combed with an ordinary comb. The hair should then be rinsed again, combed with a fine toothed comb (provided with the pack) to remove dead lice and eggs, and dried in the usual way.

One bottle of Numark Head Lice Treatment 1% w/w Cutaneous Emulsion is usually sufficient to treat one person with shoulder length hair of average thickness, a little more may be required if the person's hair is especially thick or long. It is very unlikely that more than two bottles will be required per application.

If after 7-10 days of treatment with permethrin living lice are found, treatment with permethrin should be repeated. If after 14-20 days infestation is still active treatment with an alternative product should be considered.

Children: Not recommended for children under 3 years except on advice of a doctor.

Elderly: As for adults.

4.3 Contraindications

Numark Head Lice Treatment 1% ^w/_w Cutaneous Emulsion is contraindicated in patients with a known sensitivity to the product, its components and other pyrethroids or pyrethrins.

4.2 Special Warnings and Special Precautions for use:

The active ingredient and the product are not known to be irritating to the eyes. However, if the product comes into contact with the eyes, rinse immediately with plenty of water.

Numark Head Lice Treatment 1% w/w Cutaneous Emulsion contains: Benzyl alcohol which may cause mild local irritation, Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and Propylene glycol (E 1520) may cause skin irritation. Do not use this medicine in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist.

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.

Nursing or care staff who routinely use the product should wear gloves in order to avoid potential irritation to the hands.

The effect of this product on artificial hair dyes and perms has not been determined. Although complaints are extremely rare, it is recommended to apply the product to a small section of hair first, before treating the entire scalp.

Numark Head Lice Treatment 1% w/w Cutaneous Emulsion is for external use only

Paediatric population

Only limited experience is available with Numark Head Lice Treatment 1% w/w Cutaneous Emulsion in children aged over 6 months up to 3 years. Therefore, treatment must be performed only under close specialist supervision in this age group.

Not to be used by persons known to be sensitive to the ingredients.

Numark Head Lice Treatment 1% w/w Cutaneous Emulsion may be used as normal in asthmatics, however contact your doctor or pharmacist before commencing treatment if you have any particular concerns.

Permethrin is not affected by chlorine in swimming baths, so normal swimming activities may continue after use.

As for other products used for the treatment of head lice, resistance can occur. After one week the result of the treatment should be checked. If living lice are still found, the treatment can be repeated with the same product. If, after 14 days, it is certain that the infestation is still active, it is best to switch to another active product.

Treatment failure and resistance development

Varying clinical success rates to permethrin in the treatment of head lice have been observed geographically and over time. Factors associated with treatment failure include incorrect dosing or administration errors, lack of concurrent treatment of household members, and re-infestation from community contacts. Furthermore, resistance to permethrin has been detected. However, no clear correlation could be established between lack of efficacy and mutations known to confer pyrethroid resistance. Official guidance on the appropriate use of pediculicide agents should be considered

4.5 Interaction with other medicinal products and other forms of interaction

No adverse effects reported.

4.6 Pregnancy and Lactation:

Pregnancy

For precautionary reasons, the use of Numark Head Lice Treatment 1% w/w Cutaneous Emulsion during pregnancy should be avoided unless physically acting treatment alternatives were ineffective and/or treatment with permethrin is required due to the woman's clinical condition.

Reproduction studies have been performed in mice, rats and rabbits (200 - 400 mg/kg/day orally) and have revealed no evidence of impaired fertility or harm to the foetus due to permethrin. There are however, only very limited data on the use of permethrin in pregnant women. Because animal studies are not always predictive of the human response, treatment should be considered during pregnancy only if clearly needed.

Breast-Feeding Studies

Following oral administration of permethrin in cattle have indicated that very low concentrations of permethrin are excreted in milk. However, it is not known whether permethrin is excreted in human milk. Whilst it is unlikely that the concentrations of permethrin in the milk will present any risk to the infant, consideration should be given to withholding treatment during nursing or temporarily discontinuing nursing.

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects:

Side effects are not common with Numark Head Lice Treatment 1% w/w Cutaneous Emulsion and if they occur they are usually mild and indistinguishable from the head lice infestation itself. Occasionally, skin irritation, redness or rash may occur.

If severe or prolonged signs and symptoms of scalp irritation, skin discomfort, or other undesirable effects occur in association with the use of Numark Head Lice Treatment 1% w/w Cutaneous Emulsion it should be brought to the attention of a doctor or pharmacist.

Post-marketing Data:

Adverse drug reactions (ADRs) identified during post-marketing experience with permethrin are included in table below. The frequencies are provided according to the following convention: Very common (1/10); Common (1/100)

and < 1/10); Uncommon (1/1,000 and < 1/100); Rare (1/10,000, <1/1,000); Very rare (<1/10,000); Not known (cannot be estimated from the available data).

System Organ Classes (SOC)	Frequency	Adverse Drug Reaction
Nervous system	Not known	Sensations on the skin (paraesthesia) such as tingling, pricking, skin burning sensation Alopecia

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

When applied topically, systemic overdosage with the product is unlikely due to minimal percutaneous absorption.

Indeed, there have been no reports of overdosage associated with the use of the product or other topical permethrin products. On the basis of a review of publically available animal and human-volunteer studies, it is extremely unlikely (even with intended misuse or excessive application) that the amount of permethrin or any of the other constituents, required to produce clinically-relevant toxic effects would be reached. The most likely symptoms and signs following repeated, excessive application are hypersensitivity-type reactions.

Following accidental ingestion, dizziness, nausea, vomiting, diarrhoea, CNS depression or hypotension could potentially occur. In the event of accidental ingestion of the contents of a bottle by a child a doctor should be consulted immediately. Gastric lavage should be considered within two hours of ingestion.

Symptomatic treatment is indicated if any of these reactions occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The ATC code for Numark Head Lice Treatment 1% w/w Cutaneous Emulsion is P03 A C 04 (Group: Ectoparasiticides, incl. Scabicides, insecticides and repellents). Permethrin may be classified as a Pyrethroid Pesticide. They are highly effective insecticidal neurotoxins, and are effective against head lice and their eggs. Permethrin is rapidly absorbed across the insect cuticle. The principal physiological action is the induction of electrochemical abnormalities across the membranes of excitable cells, leading to sensory hyperexcitability, inco-ordination and prostration. When presented in aqueous base, the ovicidal activity of permethrin is increased by the addition of an alcohol.

5.2 Pharmacokinetic properties

Permethrin is practically insoluble in water and is readily metabolised in humans. Hydrolysis of the ester bond, hydroxylation and elimination as glucoside conjugate is the main route of metabolism. Permethrin may persist in the fatty tissues with half-lives of 4 to 5 days in brain and fat. Permethrin does not block or inhibit cholinesterase enzymes.

Permethrin is rapidly metabolised by ester hydrolysis to inactive metabolites which are excreted primarily in the urine.

In vitro studies have shown that permethrin levels on hair are not affected by chlorine in concentrations used in swimming pools.

5.3 Preclinical safety data

The active ingredient of Numark Head Lice Treatment 1% w/w Cutaneous Emulsion is a well-known constituent of medicinal products and its safety is well documented. The results of preclinical studies do not add anything of relevance for therapeutic purposes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Propylene Glycol (E1520)

Hydroxycetyl Hydroxyethyl Dimonium Chloride
Cetostearyl Alcohol
Cetareth-20
Light Liquid Paraffin
Carbomer
Sodium Hydroxide Solution
Purified Water

6.2 Incompatibilities

None reported.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Keep container in the outer carton in order to protect from light.

Keep out of the sight and reach of children.

Do not use after the expiry date on the label and carton.

Do not use Numark Head Lice Treatment 1% ^w/_w Cutaneous Emulsion if there is any visible sign of deterioration of the lotion.

6.5 Nature and contents of container

White 59ml HDPE bottle with LDPE screw cap incorporating flip up applicator. A comb is also provided.

There are 2 pack sizes: 1 x 59ml pack and 2 x 59ml pack.

6.6 Special precautions for disposal

Shake bottle thoroughly before use.

Nursing staff routinely using Numark Head Lice Treatment 1% w/w Cutaneous Emulsion should wear gloves to avoid any irritation to the hands.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Ovelle Ltd.,
Industrial Estate,
Coe's Rd,
Dundalk,
Co. Louth,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

PL 04149/0003

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

12/06/2007

10 DATE OF REVISION OF THE TEXT

11/02/2020