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NUMARK: HEADLICE TREATMENT LEAFLET. CREATED: 08.07.19. REV: 001

PANTONE COLOURS:	
	
P7733	

PROCESS COLOURS:			
			
CYAN	MAGENTA	YELLOW	BLACK

CUTTER CONSTRUCTION:		
		
CUTTER	-	-

PAGE 1

5. HOW TO STORE HEAD LICE TREATMENT 1%

Keep out of the sight and reach of children. Do not store above 25°C. Keep the container in the outer carton in order to protect from light. Do not use after the expiry date stated on the label and carton. Do not use Head Lice Treatment 1% if you notice any visible signs of deterioration of the lotion.

6. FURTHER INFORMATION

What Head Lice Treatment 1% contains

The active substance is Permethrin.

The other ingredients are benzyl alcohol (as a preservative), propylene glycol(E 1520), hydroxycetyl hydroxyethyl dimonium chloride, cetostearyl alcohol, ceteareth-20, light liquid paraffin, carbomer, sodium hydroxide solution and purified water.

What Head Lice Treatment 1% looks like and contents of the pack

Head Lice Treatment 1% is a smooth white liquid preparation for cutaneous application.

The bottle contains 59ml of lotion.

There are 2 pack sizes: 1x59ml pack or 2x59 ml pack.

Included in each pack is a fine toothed comb which can be used to remove lice and eggs after treatment.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder and Manufacturer is Ovelle Ltd., Coe's Rd, Dundalk, Co. Louth, Ireland.

Tel: +353 (0)42 93 32304

Head Lice Treatment 1% is prepared and packaged for Numark, Amber Close, Tamworth, B77 4RP.

7. ABOUT HEAD LICE

Interesting fact about head lice

It is estimated that up to half a million children catch head lice each year. Also as with the common cold, anyone can catch lice. So if anyone in your family catches head lice, they are not alone, and it is certainly nothing to be ashamed about!

What are head lice?

Head lice are small insects (their size can vary depending on the stage of their development, but adults are usually between 2-3 mm long when fully grown) which vary in colour from greyish white to brown. They like to set up home in a warm head of human hair and have no preference for the type of hair, be it brunette or blonde, straight or curly, clean or dirty, head lice are not fussy. There is only one way for head lice to pass from one individual to another and this is by head to head contact. Head lice cannot jump, hop or fly from one person to another, and it is also unlikely for them to be passed on through towels, combs and chair backs.

Head lice spend most of their time on or near the scalp as they need warmth to survive. They grip on the hair by means of special claws and feed on the scalp by sucking blood.

The female louse will lay up to 8 oval shaped eggs every night, gluing them to the base of individual hairs. After about seven days a young louse (nymph) emerges, leaving behind it a white egg shell. These white egg shells remain glued to the hair and are known as nits. The nymph will begin feeding in the same way as the adult and within about 10 days will be mature and capable of breeding.

What to look for?

Due to their size, colour and rapid movement, head lice are difficult to see. The eggs (creamy brown) are a little easier to spot and will be found attached to individual hairs near to the scalp. In contrast, the white nits can often be seen further from the scalp, this is because as the hair grows the nits (which are still glued to the hair shaft) move with it.

The best way to find head lice and their eggs is to run a fine-toothed comb through damp parted hair looking carefully for evidence of lice. Signs to look for include faeces, cast skins or dead lice.

Louse faeces appear as black flecks like dust, often this is rubbed onto collars or the pillow at night resulting in shirts and bed clothes, becoming dirty more quickly than usual.

How to prevent head lice?

Steps that can be taken to reduce the possibility of an infection include:

- Check whole family's hair using a fine toothed detection comb on a regular basis, for any signs of head lice. If live head lice are found it is important to trace the source of the original infection. This may be someone well known to the family, but who may not be aware that they have head lice. If this person is not identified and treated, others can be quickly infected, sometimes within hours after treatment.
- If a child in your family is found to have lice, please inform their school, other parents, Health Visitor and School Nurse.

Getting the best from this treatment

In most cases a single treatment is sufficient to eliminate head lice. Use of hair mousses, gels, sprays, 2 in 1 shampoos and conditioners immediately before treatment can reduce its effectiveness.

Lice may continue to move or twitch up to 24 hours after treatment, this is normal and not a sign of treatment failure.

There is potential for head lice to develop resistance to treatments. If live lice are detected during the 7 days after the first application, a second treatment should be given on day 7. If further treatments are required consult a doctor or pharmacist, continual repetitive treatment should be avoided.

NUMARK+

Head Lice Treatment 1% w/w

Cutaneous Emulsion
Permethrin

Contains fine
toothed comb



This leaflet was prepared in July 2019.



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PAGE 2

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU.

This medicine is available without a prescription. Nevertheless you will still need to use Numark Head Lice Treatment 1% w/w Cutaneous Emulsion Head Lice Treatment 1% carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms do not improve after using Numark Head Lice Treatment 1% w/w Cutaneous Emulsion
- The name of this medicine is Numark Head Lice Treatment 1% w/w Cutaneous Emulsion hereafter referred to as Head Lice Treatment 1%

In this leaflet:

1. What Head Lice Treatment 1% is and what it is used for
2. Before you use Head Lice Treatment 1%
3. How to use Head Lice Treatment 1%
4. Possible side effects
5. How to store Head Lice Treatment 1%
6. Further information
7. About Headlice

1. WHAT HEAD LICE TREATMENT 1% IS AND WHAT IT IS USED FOR

The name of your treatment is Head Lice Treatment 1%. It is a smooth white lotion (cutaneous emulsion) containing the active ingredient **Permethrin**.

Permethrin, the active ingredient in Head Lice Treatment 1% belongs to a group of medicines called **pyrethroids**, which are anti-parasitic agents. Head Lice Treatment 1% is used for the topical treatment of head lice infestations.

2. BEFORE YOU USE HEAD LICE TREATMENT 1%

DO NOT USE HEAD LICE TREATMENT 1%

- If you are hypersensitive (allergic) to pyrethroids, pyrethrins or any of the other ingredients of Head Lice Treatment 1%.
- If you had a reaction to this product before.

Children up to 3 years:

Do not use Head Lice Treatment 1% in newborns and infants less than 6 months of age, unless your doctor tells you so. There is no adequate experience in infants and toddlers. Treatment to children up to 3 years of age should only be given under close medical supervision.

Pregnancy and Breastfeeding:

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

There have been no adverse effects reported.

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those that you have bought yourself.

Take special care with Head Lice Treatment 1%

- If you are known to be allergic to chrysanthemums or other compositae - you should only use Head Lice Treatment 1% after speaking to your doctor.
- Head Lice Treatment 1% should not irritate the eyes. However, care should be taken when applying. If accidental contact occurs, rinse immediately with plenty of water.
- Nursing or care staff who routinely use Head Lice Treatment 1% may wish to wear gloves in order to avoid possible irritation to the hands.
- If one member of the family needs treatment, it is important to check the rest of the family for head lice, and **ONLY THOSE INFECTED SHOULD BE TREATED**.
- The effect of Head Lice Treatment 1% 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.
- Head Lice Treatment 1% is not affected by the chlorine used in swimming pools, so there is no reason why you cannot swim following treatment.
- Like other products used for the treatment of head lice, resistance can occur.

Head Lice Treatment 1% contains benzyl alcohol (as a preservative), propylene glycol (E 1520), hydroxycetyl hydroxyethyl Dimonium chloride, cetostearyl alcohol, cetareth-20, light liquid paraffin, carbomer, sodium hydroxide solution and purified water.

Excipients warnings:

- Contains benzyl alcohol which may cause mild local irritation.
- Contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
- Contains 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.

3. HOW TO USE HEAD LICE TREATMENT 1%

Always use Head Lice Treatment 1% as your doctor/pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 59ml (one bottle). It is very unlikely that more than two bottles will be required per application. If necessary, a second application can be done 7 days after the first application. If after 14 days the infestation is active, it is best to switch to another active product.

Please follow these instructions carefully:



1. Shampoo the hair with a mild shampoo. Do not use a combined shampoo-conditioner or a medicated shampoo. Rinse thoroughly and towel dry so that the hair remains damp.



2. Shake the bottle thoroughly, apply sufficient Head Lice Treatment 1% to saturate the hair, roots and scalp. Work methodically through the hair paying particular attention to the areas behind the ears and around the nape of the neck.

For the majority of individuals all of the contents of this pack will be required to ensure that the hair and scalp are saturated. It is advisable to use the full bottle.



3. Leave on the hair for 10 minutes, then rinse and comb with an ordinary comb. An application for longer than 10 minutes will not give better results, but a full 10 minutes is required.



4. Rinse thoroughly with water. After this final rinse and while hair is still wet, use the fine toothed comb (provided with the pack) to remove the lice and eggs. Comb the hair in sections from the roots and work over the whole head in this way. Normal hair drying routines can then be followed.

If you use more Head Lice Treatment 1% than you should:

Head Lice Treatment 1% is for external use only. Children should be supervised during use. If you use more Head Lice Treatment 1% than recommended, rinse well with plenty of water.

IF THE PRODUCT IS ACCIDENTALLY SWALLOWED consult a doctor or go to the casualty department at your nearest hospital immediately. Take along any product that is left, the bottle and the label so that the hospital will know the product you have used.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Head Lice Treatment 1% can have side effects. However, when they occur they are usually mild and cannot be distinguished from the head lice infestation itself. Occasionally, skin irritation, redness or rash may occur. If you develop any of these, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

The assessment of the side effects is based on the following frequencies:

Common: less than 1 in 10, but more than 1 in 100 patients

Uncommon: less than 1 in 100, but more than 1 in 1,000 patients

Rare: less than 1 in 1000, but more than 1 in 10,000

Very rare: less than 1 in 10,000

Not known: frequency cannot be estimated from the available data

- Sensations on the skin (paraesthesia) such as tingling, pricking, skin burning sensation

Reporting of side effects

If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

UK Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.