

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermoline Insecticidal Shampoo for Horses.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Piperonyl Butoxide (100%) 0.084%w/w added as Piperonyl Butoxide,
Pyrethrum Extract 0.04%w/w (Pyrethrins 0.01%w/w)

3. PHARMACEUTICAL FORM

Shampoo.

4. PACKAGE SIZE

500ml, 1L, 5L, 25L

5. TARGET SPECIES

Horses

6. INDICATION(S)

For the treatment of lice infestation, routine coat care and show preparation.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Thoroughly saturate the coat with one part Dermoline Shampoo in ten parts of warm water, pouring this as required over the back of the horse. Rub this into a good lather with a soft brush adding more water as necessary. When clean, rinse thoroughly and dry. Take care to prevent the shampoo from entering the eyes or coming into contact with mucous membranes.

In cases of lice infestation use at least 1litre shampoo per horse and ensure that all parts of the body are shampooed. Leave in contact for at least 10 minutes before rinsing off. Repeat 10-14 days later. To help prevent re-infestation, the horse's stable, blankets and grooming equipment etc. should also be treated with a suitable insecticide.

8. WITHDRAWAL PERIOD

Not to be used on horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under the national passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings:

Protective clothing, including rubber gloves and apron, should be worn while using the product. Avoid contact with eyes. In case of accidental eye contact, rinse with clean, fresh water. If eye irritation persists, seek medical advice. Persons who are hypersensitive (allergic) to pyrethrum extract should handle the product with care. Treated animals should not be handled until the animal is dry. Do not eat, drink or smoke while using the product. Wash hands and exposed skin after use.

Contra – indications:

Do not use on horses with known hypersensitivity to the active ingredients. If signs of disease persist or appear consult your veterinary surgeon.

10. EXPIRY DATE

18 months from manufacture

11. SPECIAL STORAGE CONDITIONS

Pharmaceutical warnings:

Store in tightly closed original container. Keep away from food, drink or animal foodstuffs. Do not store above 25°C. Protect from frost and direct sunlight.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Environmental warnings:

Harmful to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with product or used containers. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For external use only.

For animal treatment only.

AVM-GSL

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Battle, Hayward & Bower Ltd
Crofton Drive
Lincoln
LN3 4NP
UK

16. MARKETING AUTHORISATION NUMBER

Vm 00676/4113

17. MANUFACTURER’S BATCH NUMBER

18. OTHER

Other additional information

This shampoo kills lice on horses as well as cleaning and conditioning the coat

Kills Lice.

Undesirable effects:

Some horses may be sensitive to this product; if this is suspected, wash a small area of the body 24 hours before use as directed.

General precautions:

For external use only. For animal treatment only. Keep out of the reach of children. Care must be taken to prevent the shampoo from entering the eyes and mucous membranes. This can be done by smearing petroleum jelly around those areas.

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved 11 April 2018