

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermoline Sweet Itch Lotion. - Pour-on solution.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Piperonyl Butoxide (100%) 0.5% v/v added as Piperonyl Butoxide, Pyrethrum Extract 0.4% v/v.

3. PHARMACEUTICAL FORM

Pour-on solution. Clear oily liquid

4. PACKAGE SIZE

500ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

An oily lotion for application to the mane and tail of horses as an aid in the prevention of sweet itch.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Apply the lotion in advance of the start of the season when the midge *Culicoides* become active (April). It is recommended that a small skin test under the mane should be carried out 24 hours before proper use.

First application: Apply liberally to the mane and tail with a soft brush, parting the hair on the mane and tail to apply the lotion to the skin.

Subsequent applications: Top up once or twice daily with a smaller amount of lotion throughout the spring, summer and early autumn. After shampooing the mane and tail, a heavy application should be made again.

Horses that are prone to sweet itch should be stabled if possible at dawn and dusk. If signs of disease persist or appear consult your veterinary surgeon.

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 national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Wear rubber gloves when applying 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 should handle the product with care. Treated animals should not be handled until dry. Do not eat, drink or smoke while applying the product. Wash hands and exposed skin after use.

10. EXPIRY DATE

2 years.

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original containers. Do not store above 25°C.

Keep away from food, drink and animal foodstuffs. Protect from direct sunlight.

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

Do not contaminate ponds, waterways or ditches with product or used containers. Dispose of empty container in the household refuse. Used containers should not be recycled.

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

For external use only.

AVM-GSL

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

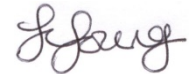
Battle, Hayward and Bower Ltd
Crofton Drive,
Lincoln.
LN3 4NP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00676/4112

17. MANUFACTURER'S BATCH NUMBER

Approved: 11/08/2017

A handwritten signature in dark ink, appearing to be 'J. King', is written below the approval date.