

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermoline Insecticidal Shampoo for Horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Piperonyl Butoxide 0.084 % w/w

Pyrethrum Extract 0.040 % w/w

(Pyrethrins 0.01 % w/w)

Excipients

Patent Blue V (E131) as dye 0.002 % w/w

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Shampoo.

A turquoise liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Horse.

4.2 Indications for use, specifying the target species

For the treatment of lice infestations in horses. Since Dermoline Shampoo for Horses contains a conditioner it can be also used as a routine grooming aid.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

To help prevent reinfestation, the animal's stable, blankets and grooming equipment etc should also be treated with a suitable insecticide. If signs of infestation persist or disease appears consult your veterinary surgeon.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

If any splashes enter the eyes wash immediately with water. Protective clothing including rubber gloves and apron should be worn while using the product. Wash hands thoroughly after use. Operators may be sensitive to the product; if this is suspected do not use the product. Do not eat, drink or smoke while using the product.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

No specific studies have been conducted in pregnant or lactating horses, however due to the low toxicity of the active ingredients, and the fact that both are included into Annex II of Regulation EC2377/90 this product is considered safe for use in pregnant and lactating horses.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For topical administration.

Thoroughly saturate the coat with one part of Dermoline Shampoo in ten parts of warm water, then pour Dermoline Shampoo as required over the back of the animal. 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 case of lice infestation use at least 1 litre of shampoo per horse to 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.

For external use only.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal Period(s)

Meat and offal: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotheapeutic group: Antiparasitic products, insecticides and repellents, ectoparasitocides for topical use, incl. insecticides, pyrethrum, combinations.

ATC vet code: QP53AC51

Pyrethrins are insecticides the precise mode of action of which remains uncertain but comprises three major stages (a) knockdown (b) paralysis (c) death. Piperonyl butoxide is a synergist which markedly enhances the potency of pyrethrins primarily by its ability to inhibit detoxification of pyrethrins by the insect.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coconut diethanolamide

Lemon grass oil

Methyl salicylate

Patent blue V (E131)

Detergent blend (consisting of sodium dodecylbenzene sulphonate, alcohol ethoxylate and sodium alcohol ether sulphate)

Citric acid anhydrous

Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4 Special precautions for storage

Store below 25°C.

Protect from frost and direct sunlight.

Store in tightly closed original container.

6.5 Nature and composition of immediate packaging

(i) 500 ml and 1 litre sizes in white HDPE containers with a polypropylene or HDPE 2 piece closure.

(ii) 5 litre white HDPE container with HDPE closure (tamper-evident).

(iii) 25 litre natural HDPE drum with black HDPE closure.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not contaminate ponds, waterways or ditches with product or used containers, and dispose of safely.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Battle Hayward and Bower Ltd
Crofton Drive
Lincoln
LN3 4NP
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10921/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27th October 2010

10 DATE OF REVISION OF THE TEXT