

## **Summary of Product Characteristics**

### **1. Name of the veterinary medicinal product.**

Radiol Insecticidal Soapless Shampoo with Conditioner.

### **2. Qualitative and quantitative composition**

<u>Active substance(s)</u>	<u>%w/w</u>
Piperonyl butoxide 100%	0.08800
(added as Piperonyl Butoxide)	
Pyrethrum extract 25%	0.04000

#### Excipients

Patent Blue V (E131)	0.00202
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For a full list of excipients, see section 6.1

### **3. Pharmaceutical form.**

Shampoo.

Turquoise liquid

### **4. Clinical particulars.**

#### **4.1 Target species;**

Horses

#### **4.2 Indications for use, specifying the target species;**

For the treatment of lice infestations in horses and as a routine grooming aid.

#### **4.3 Contra indication;**

Not to be used on horses with hypersensitivity to the active ingredients.

#### **4.4 Special warnings for each target species;**

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

To help prevent re-infestation, the animals stable, blankets, and grooming equipment etc should also be treated with a suitable insecticide.

For external use only.

#### **4.5 Special precautions for use.**

##### **i) Special precautions for use in animals**

None

##### **ii) Special precautions to be taken by the person administering the medicinal product to animals.**

Protective clothing, including rubber gloves and apron, should be worn while using the product.

Avoid contact with the 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.

#### **4.6 Adverse reactions (frequency and seriousness);**

Some horses may be sensitive to this product. If this is suspected, wash a small test 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.

#### **4.8 Interaction with other medicinal products and other forms of interaction;**

**Interaction with medicinal products** – None known.

**Other** - None known.

#### **4.9 Amounts to be administered and administration route;**

For topical administration. Thoroughly saturate the coat with one part of shampoo for in ten parts warm water by pouring the diluted shampoo 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 the horse thoroughly and dry. Take care to prevent the shampoo from entering the eyes or the mucous membranes. In cases of lice infestation, use at least 1 litre of 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.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary;**

Pyrethrins, being of natural extracts, are unlikely to cause reactions. (See also 4.3)

#### **4.11 Withdrawal period(s);**

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

### **5. Pharmacological Properties.**

**ATC vet Code QP53AC51**

#### **5.1 Pharmacodynamic properties;**

Pyrethrins are insecticides, the precise mode of action remains uncertain, but comprise 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.

#### **5.2 Pharmacokinetic properties;**

Pyrethrins I and II undergo rapid and extensive mammalian metabolism following both oral and parenteral administration which probably accounts for the low toxicity of these compounds in mammals.

Piperonyl butoxide is also undergoes metabolism in the body

Both pyrethrins and piperonyl butoxide are poorly absorbed through intact skin.

### **6 Pharmaceutical particulars**

#### **6.1 List of excipients;**

Patent Blue V (E131)

Comperlan COD

Lemon Grass Oil

Methyl Salicylate

Teepol Gold

Citric Acid, Anhydrous (for pH adjustment)

Water, Potable

## **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.**

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

## **6.5 Nature and composition of immediate packaging.**

500ml and 1 litre white, opaque, high density polyethylene bottle with white, opaque, high density polyethylene screw cap with spout or white, opaque, polypropylene screw cap with disc top.

4 litres white, opaque, high density polyethylene bottle with white, opaque, high density polyethylene screw cap (screw fit tamper-evident).

5 litres white, opaque, high density polyethylene bottle with white, opaque, high density polyethylene screw cap (screw fit).

25 litres natural, opaque, high density polyethylene drum with black, opaque, high density polyethylene screw cap.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal of unused veterinary medicinal products or waste materials derived from the use of such products -**

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

## **7. Marketing Authorisation holder.**

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

**8. Marketing Authorisation Number**

Vm00676/4111

**9. Date of the first authorisation or date of last renewal of the authorisation**

18<sup>th</sup> December 1997

**10. Date of revision of the text**

December 2008