

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dermisol Multicleanse Cutaneous Solution

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active ingredients:**

Malic acid anhydrous	2.2500 % w/v
Benzoic acid	0.1500 % w/v
Salicylic acid	0.0375 % w/v
Propylene glycol	40.0000 % v/v

For the full list of all other excipients see section 6.1

### **3. PHARMACEUTICAL FORM**

Cutaneous solution.

A clear colourless aqueous solution for topical administration.

### **4. CLINICAL PARTICULARS**

#### **4.1. Target species**

Horses, cattle, dogs and cats.

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

To encourage healing in horses, cattle, dogs and cats when this is impaired by the presence of necrotic tissue, coagulum, debris or wax. This may occur in traumatic injury, surgical wounds and otitis externa.

#### **4.3. Contraindications**

Do not use this product in the treatment of otitis externa if the animal has a ruptured ear drum.

Do not use in conjunction with other products e.g. teat dips, udder disinfectants, etc. as these will almost certainly neutralise and reduce the effectiveness of the product.

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

Contact with the eyes should be avoided as the solution may prove irritant on account of its low pH.

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

- i) Special precautions for use in animals

See section 4.7 (Use during pregnancy, lactation or lay).  
For topical application only.  
Avoid contact with the eyes.  
For external use only.

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

Care should be taken to avoid contact with the eyes because of the low pH and a possible irritant effect. If contact occurs, rinse with clean, fresh water. Seek medical attention if irritation persists. May cause skin irritation. It is recommended that gloves be worn when handling this product if you have sensitive skin. Wash hands after use.

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

None.

#### **4.7. Use during pregnancy, lactation or lay**

When used for treating udder lesions, the teats and udder should be washed and dried immediately before milking.

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

None.

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

For topical application only.

*General cleansing:* The solution should be used generously to remove dirt, grit, coagulum, etc. The residual solution will promote sloughing of de-vitalised tissues.

*Otitis externa:* Use liberally to clean the ear canal. Where hardened wax is present the solution may be left in-situ, thereby softening the wax and allowing easy removal next day. The application may be repeated 2-3 times daily as necessary.

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

Not applicable.

#### **4.11. Withdrawal periods**

<b>Cattle:</b>	Meat – Zero days Milk – Zero hours
<b>Horses:</b>	Meat – Zero days

### **5. PHARMACOLOGICAL PROPERTIES**

Dermisol aids the removal of dead tissue and embedded debris by causing maximum differential swelling between living and dead areas. This is achieved in two ways;

- The low pH causes separation of collagen molecules by rupturing the hydrogen bonding. The optimum pH to achieve this effect is between pH2 and pH3.
- The organic acids react with carboxyl and amino groups in the collagen. The insertion of the organic acid forces the collagen chains apart. In both cases, the devitalised tissues absorb water and swell markedly. Healthy tissues are unaffected because of natural barriers to the organic acids and sufficient buffering capacity to maintain a near neutral pH.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1. List of excipients**

Rose Oil  
Ethanol (96 per cent)  
Water purified

#### **6.2. Incompatibilities**

Prolonged contact with metal surfaces is inadvisable.

#### **6.3. Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

#### **6.4. Special precautions for storage**

Do not store above 25°C.  
Prolonged contact with metal surfaces is inadvisable.

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

Dermisol Multicleanse Solution is available in white low-density polyethylene bottles closed with a black urea-formaldehyde cap. The bottles contain 100 ml or 340 ml of the solution. Not all pack sizes may be marketed.

**6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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

**7. MARKETING AUTHORISATION HOLDER**

Zoetis UK Limited  
5th Floor, 6 St. Andrew Street  
London  
EC4A 3AE

**8. MARKETING AUTHORISATION NUMBER**

**Vm:** 42058/4036

**9. DATE OF THE FIRST AUTHORISATION**

**Date:** 30 April 1992

**10. DATE OF REVISION OF THE TEXT**

**Date:** June 2014



26 June 2014