SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermisol Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

Malic acid anhydrous	0.375 % w/v
Benzoic acid	0.025 % w/v
Salicylic acid	0.006 % w/v
Propylene glycol	1.750 % v/v

For the full list of all other excipients see section 6.1

3. PHARMACEUTICAL FORM

Cream
A white cream for topical application.

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 process is impaired by the presence of necrotic tissue, coagulum, debris or wax. This may occur in traumatic injury, surgical wounds, infected 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. If in doubt consult a veterinary surgeon.
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.
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, freshwater.
May cause skin irritation. It is recommended that gloves be worn when handling the 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

Apply twice daily although more frequent applications may be made if necessary.
Wounds: The cream should be spread liberally on to wound surfaces and before each new application it is advisable to wash the area with a multicleansing solution so that loose slough and cream from the previous application are removed without raising the pH.
Otitis externa: In cases of otitis externa, ears should be cleaned with a multicleansing solution prior to the introduction of the cream into the external auditory canal.

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

Not applicable.

4.11 Withdrawal periods

Cattle: Meat – zero days.
Milk – zero hours
Horses: Meat – zero days.

5. PHARMACOLOGICAL PROPERTIES

The product has antibacterial properties because of its low pH - approximately 2.3 (due to the content of malic acid, benzoic acid and salicylic acid) and the presence of propylene glycol, which together with the sloughing action create an environment in which healthy tissues can readily grow. These components also ensure that the product is adequately preserved.

ATC Vet Code: QD02AF

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Soft Paraffin
Sorbitan Sesquioleate
Cholesterol
Magnesium Sulphate Heptahydrate
Allantoin
Methyl Hydroxybenzoate
Propyl Hydroxybenzoate
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: 3 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

Epoxyphenolic resin lacquered tube with white polyethylene cap (screwfit), containing either 30 g or 100 g. 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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

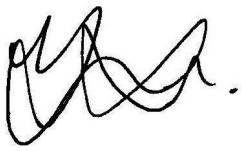
Vm 42058/4035

9. DATE OF THE FIRST AUTHORISATION

11 August 1992

10. DATE OF REVISION OF THE TEXT

August 2020



Approved: 26 August 2020