

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {TUBE LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermisol™ Cream

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Dermisol Cream is prepared from:

Propylene Glycol	1.750% v/v
Malic Acid	0.375% w/v
Benzoic Acid	0.025% w/v
Salicylic Acid	0.006% w/v

3. PHARMACEUTICAL FORM

Cream

4. PACKAGE SIZE

30 g tube
100 g tube

5. TARGET SPECIES

Horses, cattle, dogs and cats

6. INDICATION(S)

Speeds natural healing

Dermisol Cream aids removal of necrotic tissue and debris from wounds and ears, in horses, cattle, dogs and cats only.

The use of Dermisol Multicleanse Solution is recommended as a cleansing agent before each application of Dermisol Cream.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.

8. WITHDRAWAL PERIOD

Meat (Cattle/Horses) - Zero days. Milk (Cattle) - Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

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

Prolonged contact with metallic surfaces is inadvisable.

Operator warnings: 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. May cause skin irritation. It is recommended that gloves be worn when handling the product if you have sensitive skin. Wash hands after use.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the tube in the outer carton.

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

Dispose of empty packaging and any remaining product in the household or farm refuse.

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

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4035

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermisol™ Cream

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Dermisol Cream is prepared from:

Propylene Glycol	1.750% v/v
Malic Acid	0.375% w/v
Benzoic Acid	0.025% w/v
Salicylic Acid	0.006% w/v

3. PHARMACEUTICAL FORM

Cream

4. PACKAGE SIZE

30 g tube
100 g tube

5. TARGET SPECIES

Horses, cattle, dogs and cats

6. INDICATION(S)

Dermisol Cream speeds natural healing.

Dermisol Cream aids removal of necrotic tissue and debris from wounds and ears, in horses, cattle, dogs and cats only.

The use of Dermisol Multicleanse Solution is recommended as a cleansing agent before each application of Dermisol Cream.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions, Precautions etc. See enclosed package leaflet.

For external use only.

8. WITHDRAWAL PERIOD

Cattle: Meat – zero days.

Milk – zero hours.

Horses: Meat – zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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

Do not use this product in the treatment of otitis externa if the animal has a ruptured ear drum. If in doubt consult your veterinary surgeon.

Prolonged contact with metallic surfaces is inadvisable.

Operator warnings: 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. May cause skin irritation. It is recommended that gloves be worn when handling the product if you have sensitive skin. Wash hands after use.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the tube in the outer carton.

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

Dispose of empty packaging and any remaining product in the household or farm refuse.

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

For animal treatment only.

POM-VPS

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4035

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR:

Dermisol™ Cream

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Batch release site not currently stated

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermisol™ Cream

3. STATEMENT OF THE ACTIVE SUBSTANCE S AND OTHER INGREDIENTS

Dermisol Cream is a white cream. The product contains the following active ingredients:

Propylene Glycol 1.750% v/v
Malic Acid 0.375% w/v
Benzoic Acid 0.025% w/v
Salicylic Acid 0.006% w/v

4. INDICATIONS

FOR USE WITH HORSES, CATTLE, DOGS AND CATS ONLY.

- Gently removes dead tissue and debris without damaging the underlying tissues.
- Encourages rapid healing.
- Obviates the need for surgical debridement and minimises formation of scar tissues.
- An aid for treating otitis externa.
- Suitable for open or closed wound dressing techniques.

Dermisol Cream may be used to encourage wound healing in horses, cattle, dogs and cats particularly when this process is impaired by the presence of necrotic tissue, coagulum, debris or wax. This may occur in cases of traumatic injury, surgical wounds, infected wounds and otitis externa.

Dermisol Cream aids healing by removing dead and necrotic tissue from affected areas.

This is achieved by differential swelling of necrotic and healthy tissues leading to a separation of the devitalised areas and embedded debris.

5. CONTRAINDICATIONS

Do not use in the treatment of otitis externa in animals with a ruptured ear drum. If in doubt consult your 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 Dermisol.

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

6. ADVERSE REACTIONS

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7. TARGET SPECIES

Horses, cattle, dogs and cats

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Dermisol Cream is for topical use only. Dermisol Cream should be applied twice daily although more frequent applications may be made if necessary.

1. Wounds:

The cream should be spread liberally on to wound surfaces and before each new application it is advisable to wash the area so that loose slough and cream from the previous application are removed without raising the pH. Dermisol Multicleanse Solution may be used for this purpose.

2. Otitis externa:

In cases of otitis externa, ears should be cleaned prior to the introduction of Dermisol Cream into the external auditory canal. Dermisol Multicleanse Solution may be used for this purpose.

9. ADVICE ON CORRECT ADMINISTRATION

For external use only.

10. WITHDRAWAL PERIODS

Cattle: Meat - zero days.

Milk - zero hours.

Horses: Meat - zero days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Prolonged contact with metal surfaces is inadvisable.

12. SPECIAL WARNINGS

Operator Warnings:

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.

May cause skin irritation. It is recommended that gloves be worn when handling the product if you have sensitive skin.

Wash hands after use.

For animal treatment only.

Keep out of the sight and reach of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of empty packaging and any remaining product in the household or farm refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

Dermisol Cream is available in 30 g and 100 g tubes.

Dermisol aids the removal of dead tissue and embedded debris by causing maximum differential swelling between live 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.

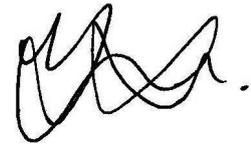
In both cases, the devitalised tissues absorb water and swell markedly.

Healthy tissue is unaffected because of natural barriers to the organic acids and sufficient buffering capacity to maintain a near neutral pH.

POM-VPS

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A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 26 August 2020