[Version 9.1, 11/2024

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noviderme 660 mg/g + 7.7 mg/g cutaneous paste for horses, cattle and sheep (DE)
Novaderma 660 mg/g + 7.7 mg/g cutaneous paste for horses, cattle and sheep (AT, BE, CZ, FR, IE, IT, HU, LU, NL, PL, PT, UK(NI))

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram paste contains:

Active substances:

Salicylic acid	660.00 mg
Methyl salicylate	7.70 mg

Excipients:

Qualitative composition of excipients and other constituents
Macrogol-6-glycerolcaprylocaprate
Sodium acetate trihydrate
Glycerol monostearate 40-55

White to yellowish paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle and sheep.

3.2 Indications for use for each target species

Hyperkeratotic skin diseases in horses, cattle and sheep.

3.3 Contraindications

Do not use in cats because of species sensitivity to the active substances.
Do not use on newborns and young animals.
Do not apply to damaged skin or mucous membranes.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
None

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product contains salicylic acid and may cause adverse effects after accidental ingestion, particularly by children. Ingestion of the related substance acetylsalicylic acid has been linked to the rare Reye syndrome in children. To avoid accidental ingestion, keep the product out of the sight

and reach of children. In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to methyl salicylate, salicylic acid or salicylates (aspirin) should avoid contact with the veterinary medicinal product.

This veterinary medicinal product can cause damage to the eye and may be irritating to the skin. Direct skin or eye contact should be avoided. Personal Protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

If skin or eye contact occurs, rinse with clean water. In case of accidental spillage onto skin or in the eyes, seek medical advice if irritation persists and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses, cattle, sheep:

Undetermined frequency (cannot be estimated from the available data):	Skin irritation, allergic reaction

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target animals.

Pregnancy and lactation:
Laboratory studies in rats have shown evidence of foetotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

When applied to the skin, salicylic acid can promote the penetration of other substances through the skin. Simultaneous administration of weak analgesics increases the effects and side effects of salicylic acid.

3.9 Administration routes and dosage

Cutaneous use.
Remove hair and surface impurities from the diseased areas and apply a thin layer of the paste with a wooden spatula.
Treatment normally consists of a singular treatment. However, if the hyperkeratosis has not been removed by the paste after one application of the veterinary medicinal product, the treatment can be repeated for another two to three consecutive days until regenerative renewal of the skin is visible. The skin areas to be treated should not exceed an area of 15 x 15 cm.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After large-scale application, systemic poisoning is possible, particularly in newborns or young animals in the first few weeks of life. Acute salicylic acid poisoning is characterized by ataxia, vomiting, dysmotility, kidney damage and respiratory paralysis.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Horses, cattle, sheep:
Meat and offal: 1 day.
Milk: 24 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QD02AF

4.2 Pharmacodynamics

After topical application to the skin, salicylic acid has a keratoplastic effect in concentrations of up to about 2% and keratolytic effects in higher concentrations. The mechanism of action is mainly based on the cleavage of disulfide and hydrogen bonds in keratin. Keratinocyte proliferation remains unaffected. In addition, the substance develops antiseptic, antipruritic and anti-inflammatory qualities.
Methyl salicylate has an irritating and hyperemic effect on the skin after local application. Erythema develops within a few minutes. An increased level of oxygen in the venous blood and an inhibition of blood platelet aggregation, which is related to the inhibition of prostaglandin synthesis, occur at the site of application. The pharmacological effect remains limited to the treated skin area.

4.3 Pharmacokinetics

After application of salicylic acid to intact skin, an absorption rate of 15–20% of the applied amount is to be expected. The absorption rate increases with increasing water content of the formulation used. Methyl salicylate is mostly split by esterases in the skin. Specific studies on dermal absorption in the target animal species are not available for either salicylic acid or methyl salicylate.

Salicylic acid is distributed quickly and completely in the organism and also enters the fetal bloodstream. Metabolism mainly takes place in the liver. Excretion is primarily renal in free form and bound to glycine and glucuronic acid. Young animals do not yet have sufficient metabolic capacity. There are differences in the metabolism and elimination rate between the individual animal species. The elimination half-lives in horses and ruminants are about half an hour.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life of after first opening the immediate packaging: 4 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Jar (polypropylene) with sealing lid and screw cap (polypropylene) containing 500 g of paste in a cardboard box.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD month YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD month YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABEL/CARTON, 1 x 500 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaderma 660 mg/g + 7.7 mg/g cutaneous paste

2. STATEMENT OF ACTIVE SUBSTANCES

1 gram paste contains:

Salicylic acid	660.00 mg
Methyl salicylate	7.70 mg

3. PACKAGE SIZE

500 g

4. TARGET SPECIES

Horses, cattle and sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Horses, cattle, sheep:
Meat and offal: 1 day.
Milk: 24 hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 4 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label on Polypropylene Jar

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaderma 660 mg/g + 7.7 mg/g cutaneous paste

2. STATEMENT OF ACTIVE SUBSTANCES

1 gram paste contains:
Salicylic acid 660.00 mg/g
Methyl salicylate 7.70 mg/g

3. TARGET SPECIES

Horses, cattle and sheep

4. ROUTES OF ADMINISTRATION

Cutaneous use

5. WITHDRAWAL PERIODS

Withdrawal periods:
Horses, cattle, sheep:
Meat and offal: 1 day.
Milk: 24 hours.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 4 months. Use by: ……

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Novaderma 660 mg/g + 7.7 mg/g cutaneous paste for horses, cattle and sheep

2. Composition

1 gram paste contains:

Active substances:

Salicylic acid	660.00 mg
Methyl salicylate	7.70 mg

White to yellowish paste.

3. Target species

Horses, cattle and sheep.

4. Indications for use

Hyperkeratotic skin diseases in horses, cattle and sheep.

5. Contraindications

Do not use in cats because of species sensitivity to the active substances.
Do not use on newborns and young animals.
Do not apply to damaged skin or mucous membranes.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product contains salicylic acid and may cause adverse effects after accidental ingestion, particularly by children. Ingestion of the related substance acetylsalicylic acid has been linked to the rare Reye syndrome in children. To avoid accidental ingestion, keep the product out of the sight and reach of children. In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to methyl salicylate, salicylic acid or salicylates (aspirin) should avoid contact with the veterinary medicinal product. This veterinary medicinal product can cause damage to the eye and may be irritating to the skin. Direct skin or eye contact should be avoided. Personal Protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
If skin or eye contact occurs, rinse with clean water. In case of accidental spillage onto skin or in the eyes, seek medical advice if irritation persists and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in rats have shown evidence of foetotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
When applied to the skin, salicylic acid can promote the penetration of other substances through the skin. Simultaneous administration of weak analgesics increases the effects and side effects of salicylic acid.

Overdose:
After large-scale application, systemic poisoning is possible, particularly in newborns or young animals in the first few weeks of life. Acute salicylic acid poisoning is characterized by ataxia, vomiting, dysmotility, kidney damage and respiratory paralysis.

7. Adverse events

Horses, cattle, sheep:

Undetermined frequency (cannot be estimated from the available data):	Skin irritation, allergic reaction.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Cutaneous use.
Remove hair and surface impurities from the diseased areas and apply a thin layer of the paste with a wooden spatula.
Treatment normally consists of a singular treatment. However, if the hyperkeratosis has not been removed by the paste after one application of the veterinary medicinal product, the treatment can be repeated for another two to three consecutive days until regenerative renewal of the skin is visible. The skin areas to be treated should not exceed an area of 15 x 15 cm.

9. Advice on correct administration

10. Withdrawal periods

Horses, cattle, sheep:
Meat and offal: 1 day.
Milk: 24 hours.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life of after first opening the immediate packaging: 4 months.
Do not use this veterinary medicinal product after the expiry date which is stated on the jar after Exp.
The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
For UK(NI) only:
Medicines should not be disposed of via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

500 g

15. Date on which the package leaflet was last revised

DD month YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstraße 14,
30827 Garbsen,
Germany
Phone: +49 51317054010
Mail: pharmakovigilanz@wdt.de

Local representatives and contact details to report suspected adverse events:

17. Other information

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novaderma 660 mg/g + 7.7 mg/g cutaneous paste for horses, cattle and sheep

2. COMPOSITION

1 gram paste contains:

Active substances:

Salicylic acid	660.00 mg
Methyl salicylate	7.70 mg

White to yellowish paste.

3. PACKAGE SIZE

500 g

4. TARGET SPECIES

Horses, cattle and sheep.

5. INDICATIONS FOR USE

Indications for use
Hyperkeratotic skin diseases in horses, cattle and sheep.

6. CONTRAINDICATIONS

Contraindications
Do not use in cats because of species sensitivity to the active substances.
Do not use on newborns and young animals.
Do not apply to damaged skin or mucous membranes.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

7. SPECIAL WARNINGS

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This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to methyl salicylate, salicylic acid or salicylates (aspirin) should avoid contact with the veterinary medicinal product.
This veterinary medicinal product can cause damage to the eye and may be irritating to the skin. Direct skin or eye contact should be avoided. Personal Protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

If skin or eye contact occurs, rinse with clean water. In case of accidental spillage onto skin or in the eyes, seek medical advice if irritation persists and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in rats have shown evidence of foetotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
When applied to the skin, salicylic acid can promote the penetration of other substances through the skin. Simultaneous administration of weak analgesics increases the effects and side effects of salicylic acid.

Overdose:
After large-scale application, systemic poisoning is possible, particularly in newborns or young animals in the first few weeks of life. Acute salicylic acid poisoning is characterized by ataxia, vomiting, dysmotility, kidney damage and respiratory paralysis.

8. ADVERSE EVENTS

Adverse events

Horses, cattle, sheep:

Undetermined frequency (cannot be estimated from the available data):	Skin irritation, allergic reaction.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
Cutaneous use.
Remove hair and surface impurities from the diseased areas and apply a thin layer of the paste with a wooden spatula. Treatment normally consists of a singular treatment. However, if the hyperkeratosis has not been removed by the paste after one application of the veterinary medicinal product, the treatment can be repeated for another two to three consecutive days until regenerative renewal of the skin is visible. The skin areas to be treated should not exceed an area of 15 x 15 cm.

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

Withdrawal periods

Horses, cattle, sheep:
Meat and offal: 1 day.
Milk: 24 hours.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life of after first opening the immediate packaging: 4 months.
Do not use this veterinary medicinal product after the expiry date which is stated on the jar after Exp.
The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
For UK(NI) only:
Medicines should not be disposed of via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

500g

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

DD month YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG
Siemensstraße 14,
30827 Garbsen,
Germany
Phone +49 51317054010
Mail: pharmakovigilanz@wdt.de

Local representatives and contact details to report suspected adverse events:

18. OTHER INFORMATION

Other information

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 4 months. Use by:…..

21. BATCH NUMBER

Lot {number}