

**Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Gerichtstraße 49
13347 Berlin
(Germany)**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A 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))**

Date: 02 April 2026

Noviderme	DE/V/0349/001/DC
WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG	DCP
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PRODUCT SUMMARY

EU procedure number	DE/V/0349/001/DC
Name, strength and pharmaceutical form	Noviderme 660 mg/g + 7.7 mg/g cutaneous paste
Applicant	WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG Siemensstrasse 14 30827 Garbsen Germany
Active substance(s)	Salicylic acid; Methyl salicylate
ATC vetcode	QD02AF
Target species	Horses, cattle and sheep
Indication for use	Hyperkeratotic skin diseases in horses, cattle and sheep

Please note that the development of the veterinary medicinal product during its lifecycle is reflected in the section "Post-authorisation procedures" of this report, as well as in the current SPC and product information. Therefore, for products that have been authorised for some time, any other part of this document may include outdated information.

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PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

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SUMMARY OF ASSESSMENT

Legal basis of original application*	Application in accordance with Article 19 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	Novaderma
Marketing authorisation holder	WDT- Wirtschaftsgenossenschaft deutscher Tierärzte eG
MS where the RP is or has been authorised	DE
Marketing authorisation number	6326457.00.00
EU procedure number	n.a.
Date of authorisation	01 December 2005
Date of completion of the original decentralised procedure	02 April 2026
Concerned Member States for original procedure	AT, BE, CZ, FR, HU, IE, IT, LU, NL, PL, PT, UK(NI)
Concerned Member States for subsequent recognition procedure	n.a.
Withdrawn CMS during original decentralised procedure	n.a.

Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES. Additionally, detailed information on protection periods has only been published in puAR since 09.02.2026.

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1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains 660.0 mg salicylic acid and 7.7 mg methyl salicylate as active substances and sodium acetate trihydrate, glycerol monostearate 40 – 55 % and macrogol 6 glycerol caprylocaprate as excipients.

The container/closure system consists of a polypropylene jar closed with a sealing lid and screw cap of polypropylene containing 500 g of paste in a cardboard box.

The choice of the formulation and the absence of preservative are justified.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

C. Production and control of starting materials

The active substances salicylic acid and methyl salicylate are established active substances described in the European Pharmacopeia/National pharmacopeia of a member state/pharmacopeia of a third country. The active substance is manufactured in accordance with the principles of good manufacturing practice.

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The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

E. Control tests on the finished product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification and their limits have been justified and are considered appropriate to adequately control the quality of the VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability tests

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

G. Other information

Not applicable.

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3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and equivalence with a reference VMP has been demonstrated, results of safety tests are not required.

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users, the environment and consumers. User warnings and precautions are not identical to those of the reference VMP as the applicant included additional appropriate user warnings and updated the user warnings in the SPC in line with the current QRD template.

A. Safety tests

User safety

The URA presented by the applicant indicates that salicylic acid and methyl salicylate can cause damage to the eye and that methyl salicylate has weak skin sensitising potential. Therefore, the recommendation to use protective gloves when administering this product is maintained.

In addition, the potential risk for children after accidental oral ingestion (including the association with Reye syndrome), the fact that hypersensitivity reactions cannot be excluded for salicylic acid (pseudo-allergies have been observed in humans), the ABCD-format as laid out in the user safety guidelines and the latest QRD template have been taken into account in user safety assessment and risk management/communication.

The following warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP:

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.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

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Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will be used to treat a small number of animals in a flock or herd.

B. Residues documentation

Residue tests

No residue depletion studies were conducted in support of this application, as this is a hybrid application submitted according to Article 19 of Regulation (EC) No 2019/6 and bioequivalence with the reference product has been demonstrated.

Maximum Residue Limits

The active substances salicylic acid and methyl salicylate are included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target tissues	Other provision	Therapeutic Classification
Salicylic acid	NOT APPLICABLE	All food producing species except fin fish	No MRL required	NOT APPLICABLE	For topical use only.	NO ENTRY
Methyl salicylate	NOT APPLICABLE	All food producing species except fin fish	No MRL required	NOT APPLICABLE	For topical use only.	NO ENTRY

The excipients are allowed substances for which Table I of the Annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required.

Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:

Horses, cattle, sheep:

Meat and offal: 1 day.
Milk: 24 hours.

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4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and equivalence with a reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

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POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which have been made after the original procedure, which are important for the quality, safety or efficacy of the VMP.

Changes:

None.