SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Footvax emulsion for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substances:

Dichelobacter nodosus serogroup A, strain 6, inactivated	10 µg pili
Dichelobacter nodosus serotype B1, strain 44, inactivated	10 µg pili
Dichelobacter nodosus serotype B2, strain 58, inactivated	10 µg pili
Dichelobacter nodosus serogroup C, strain 8, inactivated	10 µg pili
Dichelobacter nodosus serogroup D, strain 16, inactivated	10 µg pili
Dichelobacter nodosus serogroup E, strain 5, inactivated	10 µg pili
Dichelobacter nodosus serogroup F, strain 66, inactivated	10 µg pili
Dichelobacter nodosus serogroup G, strain 52, inactivated	10 µg pili
Dichelobacter nodosus serogroup H, strain 340, inactivated	10 µg pili
Dichelobacter nodosus serogroup I, strain 109, inactivated	5 x 10^8 cells

Adjuvants:

Light mineral oil NF	60% v/v
Manide oleate	4.5% v/v

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.015% w/v
Sodium chloride solution	

White to off white oily emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the active immunisation of sheep as an aid to the prevention of footrot and reduction of lesions of footrot caused by serogroups and/or serotypes of *Dichelobacter nodosus*.

3.3 Contraindications

Do not vaccinate sheep within 6–8 weeks of shearing.
Do not use in lactating dairy sheep.
Do not vaccinate ewes in the period of 4 weeks before lambing to 4 weeks after lambing.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Sheep destined for show or sale should not be vaccinated within the previous 6 months because of the occurrence of a well-defined, inactive lump at the site of injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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

3.6 Adverse events

Sheep:

Very common (>1 animal / 10 animals treated):	Injection site swelling.[1]
Rare (1 to 10 animals / 10,000 animals treated):	Lameness.[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction.[3]

[1] The vaccine may cause a reaction at the site of injection. This may range from a slight swelling to a well-defined lump of about 3 cm to 5 cm or even 8 cm diameter, from about 24 hours after injection to 8 days after injection. These swellings generally remain inactive and may resolve completely within 4-6 weeks, but frequently swellings persist for at least 10 weeks. Occasionally, these swellings may be large, painful and unsightly, with the formation of abscesses which may burst and discharge, particularly if any contaminating skin bacteria are introduced at the time of injection. Partial or complete resolution within 10 weeks of inoculation can be expected. Reactions to second doses develop more slowly but the formation of necrotic lesions is rare. Occasionally abscesses may be noted on macroscopic examination of injection sites. Subcutaneous necrosis and inflammation may be noted on microscopic examination of injection sites.
[2] Generalised and transitory lameness, which is thought to be due to a local immunological reaction, has been reported after vaccination, occurring within 24 hours of vaccination and normally persisting for no more than 48 hours.
[3] In such cases adrenalin or antihistamines should be administered without delay.

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

Pregnancy:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided on a case by case basis.

3.9 Administration routes and dosage

Administration: Subcutaneous use.
Dose: 1 ml.

Primary vaccination: Two vaccinations, at an interval of 6 weeks. This vaccine should be administered by subcutaneous injection underneath a skinfold in the neck at least 5 – 8 cm behind the ear to strictly avoid muscle and nervous tissues in the neck.
Shake bottle thoroughly before use.

As the vaccine contains an oil adjuvant it is rather viscous. It will aid administration in cold weather if the vaccine is gently warmed by immersion in warm water (not hot) for 3-4 minutes before use.
Particularly strict precautions should be taken against contamination of the vaccine. Sterile syringes and needles should be used and the injection made through an area

of clean, dry skin, taking strict precautions against contamination in order to reduce the possibility of abscess formation.

Vaccination programmes:
These should be tailored to meet individual flock requirements which will vary from season to season according to the actual or likely incidence of footrot.
Wherever possible 'whole flock' vaccination programmes should be adopted. By this means disease incidence in the flock will decline and subsequent disease risk from the environment will be greatly reduced.

Prevention programme:
Commence vaccination with a single dose of vaccine. Further doses of vaccine will be required according to the flock disease status and/or the climatic conditions. If, after 4-6 weeks significant levels of disease remain in the flock or climatic conditions conducive to footrot persist, administer a further dose. Otherwise delay this dose until conditions favour re-emergence of the disease.
Subsequent doses should also be administered according to prevailing conditions. Thus, with severe and constant disease challenge, revaccination may be necessary at 4-5 monthly intervals; conversely under favourable conditions revaccination may be delayed until the incidence of disease challenge increases or climatic conditions worsen.
It should be noted that these adverse conditions tend to occur in the UK between March and May and between October and December thus, vaccination should normally be completed shortly before these periods if problems are anticipated.

Treatment programme:
A single dose of vaccine should be given to the flock immediately the disease becomes apparent. For maximum effect, treatment with the vaccine should be combined with the use of a footbath and antibiotic treatment.

Revaccination should be as stated in the prevention programme, which should then be continued on the farm as the key element of the overall flock foot care programme.

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

At a 2-fold overdose, no other effects other than those described under section 3.6 have been observed.

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

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AB03.

To stimulate active immunity against serogroups and serotypes of *Dichelobacter nodosus* included in the vaccine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: Use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

20 ml, 50 ml or 250 ml low density polyethylene flexible pack closed with a pharmaceutical grade butyl rubber bung held in place with an aluminium seal.

Pack sizes:
Cardboard box containing 1 x bottle of 20 ml (20 doses), 50 ml (50 doses) or 250 ml (250 doses).
Not all pack sizes may be marketed.

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.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4110

8. DATE OF FIRST AUTHORISATION

28 October 2005.

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

September 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 12 November 2025