SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Footvax

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	**Per 1 ml dose**
D. nodosus serotype A	10 µg pili
D. nodosus serotype B1	10 µg pili
D. nodosus serotype B2	10 µg pili
D. nodosus serotype C	10 µg pili
D. nodosus serotype D	10 µg pili
D. nodosus serotype E	10 µg pili
D. nodosus serotype F	10 µg pili
D. nodosus serotype G	10 µg pili
D. nodosus serotype H	10 µg pili
D. nodosus serotype I	5 x 10^8 cells

Excipients

Adjuvant	
Light mineral oil NF	60%
Manide oleate	4.5%

Preservative

Thiomersal	0.015%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for Injection.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each 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.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals.

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user: This 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 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 doctor: This product contains mineral oil. Even if small amounts have been injected, accidental injection with this 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.

4.6 Adverse reactions (frequency and seriousness)

The vaccine may cause a reaction at the site of injection. This may range from a slight swelling from about 24 hours after injection, to a well-defined lump of about 3 cm diameter 8 days after injection. These may further increase in size to 5 or even 8 cm diameter but these swellings generally remain inactive and may resolve completely within 4-6 weeks. Frequently swellings persist for at least ten weeks. Occasionally, however, 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. Even so, partial or complete resolution within ten 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.
Occasional hypersensitivity reactions may occur. In such cases, an appropriate dose of adrenalin and/or antihistamines should be administered without delay.
On rare occasions variable incidence of generalised lameness has been reported in vaccinated sheep. This is thought to be due to a local immunological reaction in the feet and is transitory in nature, occurring within 24 hours of vaccination and normally persisting for no more than 48 hours. Treatment is seldom necessary.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 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 except those mentioned above. 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.

4.9 Amounts to be administered and administration route

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 Footvax 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.

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

When the vaccine is given at twice the recommended dose a reaction similar to that described in section 4.6 should be expected.
In some cases, skin lesions with overt pus accumulation or slight necrosis develop. This necrotic skin lesion and pus accumulation occurs less frequently following a second injection. There are no adverse clinical signs in animals following treatment with 2x dose. There is no specific antidote.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against serotypes of *Dichelobacter nodosus* included in the vaccine.
ATCvet code: QI04AB03.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Manide oleate
Light mineral oil NF
Sodium chloride solution

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 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.

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 the local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4110

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

19 December 2024

Gavin Hall
Approved: 19 December 2024