Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Footvax Emulsion for Injection for Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:

Dichelobacter nodosus serotype A	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype B_1	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype B_2	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype C	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype D	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype E	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype F	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype G	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype H	10 µg pili equivalent to ≥400 potency units*
Dichelobacter nodosus serotype I	5×10^8 cells/ml equivalent to ≥ 400 potency units*

* based on the potency test

Adjuvants:

Light mineral oil	60.0 % v/v
Mannide oleate	4.5 % v/v

Excipients:

Preservative: thiomersal	0.015 % w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep from 4 weeks of age.

4.2 Indications for use, specifying the target species

For the active immunisation of sheep against footrot caused by *Dichelobacter nodosus* for the purposes of reducing the risk of a clinical infection due to *Dichelobacter nodosus*.
Onset of immunity: 3 weeks after the primary vaccination course.
Duration of immunity: 6 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
Do not vaccinate sheep within 6 - 8 weeks of shearing.

Sheep destined for show or sale should not be vaccinated within the previous 6 months because of possible severe local reactions. Such reactions may produce local pigment changes in wool.

4.5 Special precautions for use

Special precautions for use in animals
Occasional hypersensitivity reactions may occur. In such cases adrenalin or antihistamines should be administered without delay.

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 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 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 oil in 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.

On rare occasions, variable incidence of generalised lameness has been reported in vaccinated sheep and is transitory in nature, occurring within 24 hours of vaccination and normally persisting for no more than 48 hours.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not vaccinate ewes during the period 4 weeks before lambing to 4 weeks after lambing.
Do not use in lactating dairy sheep.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

Dose: 1 ml.
Administration: By subcutaneous injection. The site for injection is on the side of the neck 2–3 inches behind the ear.

Thoroughly shake the vaccine before use.
The vaccine contains an oil adjuvant and therefore is viscous. It will aid administration in cold weather if the vaccine is gently warmed by immersion in warm water (not hot water) for 3-4 minutes before use.

Dosage schedule:
The initial course consists of two doses.

Vaccination programme:
Administer a single dose. Six weeks later give a second dose of vaccine.

Revaccination programme:
In areas with constant disease challenge, re-vaccination should take place at 6 monthly intervals.
Syringes and needles should be sterilised before use 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.

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

A swelling or reaction as described in section 4.6 may occur at the injection site following administration of an overdose.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code: QI04AB03.
Stimulates the production of antibodies to the *Dichelobacter nodosus* antigens contained in the vaccine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light mineral oil
Mannide oleate
Thiomersal
Formaldehyde
Sodium chloride

6.2 Major 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: 24 months.
Shelf-life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard box containing a flexible polyethylene vial of 50 ml (50 doses) with rubber stopper and aluminium cap.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
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Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/232/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 20 February 2004
Date of last renewal: 19 February 2009

10 DATE OF REVISION OF THE TEXT

August 2021