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	0.6 ml
Mannide oleate	0.045 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.15 mg
Sodium chloride	
Formaldehyde	

White to off white oily emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Sheep from 4 weeks of age.

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

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 reaction[1], Injection site swelling[1,2].
Rare (1 to 10 animals / 10,000 animals treated):	Lameness[3].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[2], Injection site abscess[2] Hypersensitivity reaction[4].

[1] 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.

[2] 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. 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.
[3] occurring within 24 hours of vaccination and normally persisting for no more than 48 hours.
[4] 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 and lactation:
Do not vaccinate animals during the period 4 weeks before lambing to 4 weeks after lambing.
Do not use in lactating dairy sheep.

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

Dose: 1 ml.
Administration: By subcutaneous use. 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.

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.

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.

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

A swelling or reaction as described in section 3.6 may occur at the injection site following administration of an overdose.

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

Meat and offal: Zero days.
Milk: Not authorised for use in animals producing milk for human consumption.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AB03.

Stimulates the production of antibodies to the *Dichelobacter nodosus* antigens contained 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: 24 months.
Shelf-life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Cardboard box containing a flexible polyethylene vial of 50 ml (50 doses) with rubber stopper and aluminium cap.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/232/001

8. DATE OF FIRST AUTHORISATION

20 February 2004

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

06 December 2024

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).