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, serotype A, strain 6, Inactivated	10 µg pili
Dichelobacter nodosus, serotype B_1, strain 44, Inactivated	10 µg pili
Dichelobacter nodosus, serotype B_2, strain 58, Inactivated	10 µg pili
Dichelobacter nodosus, serotype C, strain 8, Inactivated	10 µg pili
Dichelobacter nodosus, serotype D, strain 16, Inactivated	10 µg pili
Dichelobacter nodosus, serotype E, strain 5, Inactivated	10 µg pili
Dichelobacter nodosus, serotype F, strain 66, Inactivated	10 µg pili
Dichelobacter nodosus, serotype G, strain 52, Inactivated	10 µg pili
Dichelobacter nodosus, serotype H, strain 340, Inactivated	10 µg pili
Dichelobacter nodosus, serotype I, strain 109, Inactivated	5×10^8 cells

Adjuvants:

Light mineral oil, NF	60% v/v
Mannide 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	0.85% w/v
Formaldehyde	

White to off white oily emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

Active immunisation of sheep from 12 weeks of age against footrot caused by various serotypes of *Dichelobacter nodosus*, which as a prophylactic vaccination leads to protection against the footrot, or as a therapeutic vaccination in already diseased animals reduces the duration of healing.

Onset of immunity: 4 weeks after the second vaccination (primary vaccination).

Duration of immunity: 1 year, if footrot occurs once a year; with severe and constant disease challenge revaccination may be necessary at 4-5 monthly intervals.

3.3 Contraindications

Do not vaccinate sheep within 6–8 weeks after shearing.

3.4 Special warnings

For prophylactic use, vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Sheep intended for exhibition or sale should not be vaccinated in the previous 6 months because of the possible occurrence of demarcated swelling at the injection site.

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], injection site lump[1].
Rare (1 to 10 animals / 10,000 animals treated):	Lameness[2]. Elevated temperature, apathy, decreased appetite.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[3].

[1] These may appear from about 24 hours after injection to 8 days after injection with a range from a slight swelling to a well-defined lump of max. 5 cm diameter. These swellings generally remain inactive and may resolve completely within 5-6 weeks without treatment.

[2] Generalised and transitory, occurring within 24 hours of vaccination and normally persisting no longer than 48 hours. It can be assumed that a transient local immunological reaction takes place in the limbs. Treatment is rarely required.

[3] In such cases an appropriate dose of adrenalin and/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.
{< > to be adjusted nationally}

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not vaccinate ewes in the period of 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 made on a case by case basis.

3.9 Administration routes and dosage

Administration: subcutaneous use.
Dose: 1 ml, regardless of race, weight and age.

This vaccine should be administered by subcutaneous injection underneath a skin fold in the neck (area of clean, dry skin) 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, in cold weather it will aid administration if the vaccine is gently warmed by immersion in warm water (not hot) for 3-4 minutes before use.

For herd rehabilitation, all animals in a herd, including rams and weaned lambs, should be included in the vaccination programme.
The therapeutic vaccination in already ill animals should be carried out in conjunction with other measures (foot baths, spray treatment).

Primary vaccination: Two vaccinations, at an interval of 4-6 weeks.
Revaccinations: After 6 months; in particularly vulnerable areas after 4-5 months.

In areas where the footrot occurs only once a year, an annual revaccination is sufficient.
It should be re-vaccinated about 6 weeks before the time at which the herd concerned is particularly exposed to the risk of footrot disease.

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

After administration of the 2-fold vaccine dose, a defined swelling (up to 8x8 cm in diameter) may occur at the injection site up to 7 days after vaccination, which resolves within 5 - 6 weeks. In some cases, skin lesions with open pus accumulation and mild necrosis have been observed. These necrotic skin lesions with pus accumulation are less common after a second injection. A specific antidote is not available.

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.
{< > to be adjusted nationally}

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: Q104AB03.

To stimulate active immunity against serotypes of *Dichelobacter nodosus* contained in the vaccine.

K-agglutinating antibodies against each serotype contained in the vaccine are developed 6 weeks after a single immunisation (at least a titre of 1:400).

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: 2-4 hours.

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

Polyethylene – Flexipack bottles, type LDPE (Eu.Ph.) with 20 ml (20 doses), 50 ml (50 doses), closed with bromobutyl rubber stoppers and aluminium caps.

Pack sizes:
Cardboard box containing 1 flexible bottle of 20 ml (20 doses).
Cardboard box containing 1 flexible bottle of 50 ml (50 doses),

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>.
{< > to be adjusted nationally}

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

{Name}
{to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.
{to be completed nationally}

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

{MM/YYYY}
{to be completed nationally}

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).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Footvax emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:
D. nodosus serotypes A, B_1, B_2, C, D, E, F, G and H: 10 µg pili
D. nodosus serotype I: 5×10^8 cells

3. PACKAGE SIZE

20 ml (20 doses)
50 ml (50 doses)

4. TARGET SPECIES

Sheep

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 2-4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name or company name or logo name of the marketing authorisation holder}
{< > to be adjusted nationally}

14. MARKETING AUTHORISATION NUMBERS

{number}
{< > to be adjusted nationally}

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Polyethylene-type LDPE bottle LABEL (20 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Footvax

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

D. nodosus serotypes A, B_1, B_2, C, D, E, F, G, H and I; see package leaflet.

20 ml (20 doses)
50 ml (50 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 2-4 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Footvax emulsion for injection for sheep

2. Composition

Each dose (1 ml) contains:

Dichelobacter nodosus, serotype A, strain 6, Inactivated	10 µg pili
Dichelobacter nodosus, serotype B_1, strain 44, Inactivated	10 µg pili
Dichelobacter nodosus, serotype B_2, strain 58, Inactivated	10 µg pili
Dichelobacter nodosus, serotype C, strain 8, Inactivated	10 µg pili
Dichelobacter nodosus, serotype D, strain 16, Inactivated	10 µg pili
Dichelobacter nodosus, serotype E, strain 5, Inactivated	10 µg pili
Dichelobacter nodosus, serotype F, strain 66, Inactivated	10 µg pili
Dichelobacter nodosus, serotype G, strain 52, Inactivated	10 µg pili
Dichelobacter nodosus, serotype H, strain 340, Inactivated	10 µg pili
Dichelobacter nodosus, serotype I, strain 109, Inactivated	5 x 10^8 cells

Adjuvants:

Light mineral oil, NF	60% v/v
Mannide oleate	4.5% v/v

Excipient:

Thiomersal	0.015% w/v

K-agglutinating antibodies against each serotype contained in the vaccine are developed 6 weeks after a single immunisation (at least one titre of 1:400).

White to off white oily emulsion.

3. Target species

Sheep.

4. Indications for use

Active immunisation of sheep from 12 weeks of age against footrot caused by various serotypes of *Dichelobacter nodosus*, which as a prophylactic vaccination leads to protection against the footrot, or as a therapeutic vaccination in already diseased animals reduces the duration of healing.

Onset of immunity: 4 weeks after the second vaccination (primary vaccination).

Duration of immunity: 1 year, if footrot occurs once a year; with severe and constant disease challenge, revaccination may be necessary at 4-5 monthly intervals.

5. Contraindications

Do not vaccinate sheep within 6–8 weeks after shearing.

6. Special warnings

Special warnings:
For prophylactic use, vaccinate healthy animals only.

Special precautions for safe use in the target species:
Sheep intended for exhibition or sale should not be vaccinated in the previous 6 months because of the possible occurrence of demarcated swelling at the injection site.

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.

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

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 made on a case by case basis.

Overdose:
After administration of the 2-fold vaccine dose, a defined swelling (up to 8x8 cm in diameter) may occur at the injection site up to 7 days after vaccination, which resolves within 5 - 6 weeks. In some cases, skin lesions with open pus accumulation and mild necrosis have been observed. These necrotic skin lesions with pus accumulation are less common after a second injection. A specific antidote is not available.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Sheep:

Very common	Injection site swelling[1], injection site lump[1].

(>1 animal / 10 animals treated):	
Rare (1 to 10 animals / 10,000 animals treated):	Lameness[2]. Elevated temperature, apathy, decreased appetite.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[3].

[1] These may appear from about 24 hours after injection to 8 days after injection with a range from a slight swelling to a well-defined lump of max. 5 cm diameter. These swellings generally remain inactive and may resolve completely within 5-6 weeks without treatment.
[2] Generalised and transitory, occurring within 24 hours of vaccination and normally persisting no longer than 48 hours. It can be assumed that a transient local immunological reaction takes place in the limbs. Treatment is rarely required.
[3] In such cases an appropriate dose of adrenalin and/or antihistamines should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

8. Dosage for each species, routes and method of administration

Dose: 1 ml.
Administration: subcutaneous use.

This vaccine should be administered by subcutaneous injection underneath a skin fold in the neck (area of clean, dry skin) 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, in cold weather it will aid administration if the vaccine is gently warmed by immersion in warm water (not hot) for 3-4 minutes before use.

For herd rehabilitation, all animals in a herd, including rams and weaned lambs, should be included in the vaccination programme.
The therapeutic vaccination in already ill animals should be carried out in conjunction with other measures (foot baths, spray treatment).

Primary vaccination: Two vaccinations, at intervals of 4-6 weeks.
Revaccinations: After 6 months; in particularly vulnerable areas after 4-5 months.

In areas where the footrot occurs only once a year, an annual revaccination is sufficient. It should be re-vaccinated about 6 weeks before the time at which the herd concerned is particularly exposed to the risk of footrot disease.

9. Advice on correct administration

See above section for a full description of the method of application.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 2-4 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.
{< > to be adjusted nationally}

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{< > to be adjusted nationally}

Pack sizes:
Cardboard box containing 1 flexible bottle of 20 ml (20 doses).
Cardboard box containing 1 flexible bottle of 50 ml (50 doses).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}
{to be completed nationally}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<Manufacturer responsible for batch release:> {to be adjusted nationally if included in the above}
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<Local representative< and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

17. Other information

{to be completed nationally}