PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Footvax

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains ten strains of inactivated *Dichelobacter nodosus* with an oil adjuvant.

One dose of 1 ml contains:

D. nodosus serotypes A, B1, B2, C, D, E, F, G, H	10 µg pili each
D. nodosus serotype I	5×10^8 cells

Preservative: Thiomersal 0.015% w/v

3. PHARMACEUTICAL FORM

Emulsion for Injection

4. PACKAGE SIZE

20 ml
50 ml
250 ml

20 doses
50 doses
250 doses

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

Footrot vaccine for sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: 1 ml by subcutaneous injection.
Read instructions before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings:
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.

10. EXPIRY DATE

EXP:
Once opened use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read instructions before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For Animal Treatment only.
POM-VPS
To be supplied only on veterinary Prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive,
Magna Business Park
Citywest Road
Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4553

17. MANUFACTURER'S BATCH NUMBER

Batch no:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Footvax

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of 1 ml contains:
D. nodosus serotypes: A, B1, B2, C, D, E, F, G, H 10 µg pili each and *D. nodosus* serotype I 5 x 10^8 cells and Thiomersal.

3. PHARMACEUTICAL FORM

Emulsion for Injection

4. PACKAGE SIZE

20 doses
50 doses
250 doses

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

Footrot vaccine for sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: SC.
Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2–8 °C).
Do not freeze.
Protect from light.
Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.
POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Read package leaflet before use.

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4553

17. MANUFACTURER'S BATCH NUMBER

Batch no.

PACKAGE LEAFLET FOR:

Footvax

Emulsion for injection.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturers for the batch release[1]:
MSD Animal Health UK Limited
Walton Manor, Walton, Milton Keynes
Buckinghamshire, MK7 7AJ
United Kingdom

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

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Footvax
Emulsion for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

One dose (1 ml) contains:

Active ingredients:

Dichelobacter nodosus serotype A	10 µg pili
Dichelobacter nodosus serotype B1	10 µg pili
Dichelobacter nodosus serotype B2	10 µg pili
Dichelobacter nodosus serotype C	10 µg pili
Dichelobacter nodosus serotype D	10 µg pili
Dichelobacter nodosus serotype E	10 µg pili
Dichelobacter nodosus serotype F	10 µg pili

Dichelobacter nodosus serotype G	10 µg pili
Dichelobacter nodosus serotype H	10 µg pili
Dichelobacter nodosus serotype I	5 x 10^8 cells

Excipients:

Thiomersal (Preservative)	0.015%
Light mineral oil NF (adjuvant)	60%
Manide oleate (adjuvant)	4.5%

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this leaflet, please

inform your veterinary surgeon.

7. TARGET SPECIES

Sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose: 1 ml

Administration:
Initial Course: Two doses, 6 weeks apart 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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.
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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C to 8 °C).
Protect from light.
Do not freeze.
Once opened use immediately.
Do not use after the expiry date stated on the label and carton.

12. SPECIAL WARNING(S)

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.

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.

Use during pregnancy or lactation

Can be used during pregnancy.
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 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.

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 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.

Incompatibilities

Do not mix with any other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

15. OTHER INFORMATION

For animal treatment only.

Pack sizes:
20 ml, 50 ml or 250 ml.
Not all pack sizes may be marketed.

MA number: Vm 01708/4553

Legal category:

POM-VPS
To be supplied only on veterinary prescription.

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

Approved 02 December 2021