PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX
Plastic box with 5 x 1 dose vials of vaccine and 5 x 0.5 ml solvent vials (glass)
Plastic box with 25 x 1 dose vials of vaccine and 25 x 0.5 ml solvent vials (glass)
Cardboard box with 10 x 50 doses of vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Myxo-RHD PLUS lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live myxoma vectored RHD virus strain 009: $10^{3.0}$ - $10^{5.8}$ FFU/dose.
Live myxoma vectored RHD virus strain MK1899: $10^{3.0}$ - $10^{5.8}$ FFU/dose.

3. PACKAGE SIZE

5 x 1 dose of vaccine including solvent
25 x 1 dose of vaccine including solvent
10 x 50 doses of vaccine

4. TARGET SPECIES

Rabbits

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 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

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5050

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX (SOLVENT ONLY)
Cardboard box with 10 x 10 ml solvent vials (glass)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Nobivac Myxo-RHD PLUS

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3. PACKAGE SIZE

10 x 10 ml

4. TARGET SPECIES

Rabbits

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5050

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VACCINE GLASS VIAL LABEL – 1 dose / 50 doses glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Myxo-RHD PLUS

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live myxoma vectored RHD viruses

1 dose
50 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

SC

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE DILUENT/SOLVENT

SOLVENT LABEL
0.5 ml and 10 ml glass vial

1. NAME OF THE SOLVENT

Solvent for Nobivac Myxo-RHD PLUS

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.5 ml
10 ml

3. ROUTES OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD AH logo

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Myxo-RHD PLUS lyophilisate and solvent for suspension for injection for rabbits

2. COMPOSITION

Each dose (0.2 ml or 0.5 ml) of reconstituted vaccine contains:

Active substances:
Live myxoma vectored RHD virus strain 009: $10^{3.0}$ - $10^{5.8}$ FFU *
Live myxoma vectored RHD virus strain MK1899: $10^{3.0}$ - $10^{5.8}$ FFU*

*Focus Forming Units

Lyophilisate: off-white or cream-coloured pellet.
Solvent: clear colourless solution.

3. TARGET SPECIES

Rabbits.

4. INDICATIONS FOR USE

For active immunisation of rabbits from 5 weeks of age onwards to reduce mortality and clinical signs of myxomatosis and rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV1) and RHD type 2 virus (RHDV2).

Onset of immunity: 3 weeks.
Duration of immunity: 1 year.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.

High levels of maternally derived antibodies against myxoma virus and/or RHD virus can potentially reduce the efficacy of the product. To ensure the full duration of immunity, vaccination from 7 weeks of age is advised in this case.

Rabbits that have been vaccinated previously with another myxomatosis vaccine, or that have experienced natural myxomatosis infection in the field, may not develop a proper immune response against rabbit haemorrhagic disease following vaccination.

Pregnancy:
Can be used during pregnancy.

Fertility:
No safety study on the reproductive performance has been conducted in male rabbits (bucks). Therefore, the vaccination of breeding bucks is not recommended.

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 (symptoms, emergency procedures, antidotes):
In addition to the signs observed after single dose vaccination, a mild swelling of the local lymph nodes may be observed within the first 3 days after the administration of a ten-fold overdose.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant competent authority on the current vaccination policies, as these activities may be prohibited in a country on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

7. ADVERSE EVENTS

Rabbits:

Common (1 to 10 animals / 100 animals treated):	Hyperthermia[1]. Injection site swelling.[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site necrosis[3], injection site scab[3], injection site crust[3], injection site hair loss[3]. Hypersensitivity reaction[4]. Myxomatosis[5]. Anorexia, lethargy.

[1] Transient temperature increase of 1 – 2 °C.
[2] A small, non-painful swelling (maximum 2 cm diameter) within the first two weeks after vaccination. The swelling will resolve completely by 3 weeks after vaccination.
[3] In pet rabbits.
[4] Sometimes fatal.

[5] Mild clinical signs of myxomatosis may occur within 3 weeks of vaccination.

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 using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Subcutaneous use.

Primary vaccination:
Administer one dose to rabbits from 5 weeks of age onwards.

Revaccination:
Revaccinate annually.

9. ADVICE ON CORRECT ADMINISTRATION

Ensure that the lyophilisate is completely reconstituted before use.
Reconstituted product: off-pink or pink coloured suspension.

Single-dose vial
Reconstitute a single dose vial containing lyophilisate with 0.5 ml of the supplied solvent. Administer the total contents of the vial.

Multi-dose vial
Reconstitute a multi-dose vial containing lyophilisate with 10 ml of the supplied solvent. Administer 0.2 ml per animal.

For proper reconstitution of the multidose vial, use the following procedure:

1. Add 1 – 2 ml of solvent to the 50-dose vaccine vial and ensure that the lyophilisate is fully dissolved.
2. Withdraw the reconstituted vaccine concentrate from the vial and inject it back into the solvent vial.
3. Ensure that the resulting vaccine suspension in the solvent vial is properly mixed.
4. Use the vaccine suspension within 4 hours of reconstitution. Any reconstituted vaccine remaining at the end of this time should be discarded.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Solvent:
No special precautions for storage.

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

Shelf life after reconstitution according to directions: 4 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. 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

Marketing authorisation number:
Vm 01708/5050

Pack sizes:
- Plastic box with 5 x 1 dose vials of vaccine and 5 vials containing 0.5 ml of solvent.
- Plastic box with 25 x 1 dose vials of vaccine and 25 vials containing 0.5 ml of solvent.
- Cardboard box with 10 x 50 doses vials of vaccine; and cardboard box with 10 x 10 ml vials of solvent.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
MSD Animal Health UK Limited
Tel.: +44 (0)1908 685685

17. OTHER INFORMATION

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.

The vaccine is intended to stimulate immunity against myxoma virus and rabbit haemorrhagic disease viruses in rabbits.

The vaccine strains are myxoma viruses expressing the capsid protein gene of classical or type 2 RHD viruses. As a consequence, rabbits are immunised against myxoma virus and both classical and type 2 RHD virus.

The vector technology used to develop the vaccine strains allows the RHD virus components to be produced *in vitro* instead of using live rabbits for cultivation.

After infection with virulent field myxoma virus some vaccinated animals may develop a few very small swellings, especially on hairless places of the body, which quickly form scabs. These scabs usually disappear within 2 weeks. The scabs are only observed in animals with active immunity and have no influence on the general

health, appetite or behaviour of the rabbit. Recent or latent infection with field myxoma virus seems to play a role in the development of the mild clinical signs of myxomatosis that may occur within 3 weeks after vaccination.

Approved 14 May 2024