SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Myxo-RHD PLUS Lyophilisate and Solvent for Suspension for Injection for Rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Active substance:
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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

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

4. CLINICAL PARTICULARS

4.1 Target species

Rabbits.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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 an adequate immune response against rabbit haemorrhagic disease following vaccination.

4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

A transient temperature increase of 1 – 2 °C can commonly occur. A small, non-painful swelling (maximum 2 cm diameter) at the injection site is commonly observed within the first two weeks after vaccination. The swelling will resolve completely by 3 weeks after vaccination. In pet rabbits, local reactions at the injection site such as necrosis, scabs, crusts or hair loss may occur in very rare cases. Serious hypersensitivity reactions, which may be fatal, may occur after vaccination in very rare cases. The appearance of mild clinical signs of myxomatosis may occur within 3 weeks of vaccination in very rare cases. Recent or latent infection with field myxoma virus seems to play a role in this to a certain extent.
Anorexia and lethargy may occur in very rare cases.

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:
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.

4.8 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.

4.9 Amounts to be administered and administration route

Subcutaneous use.

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

Revaccination:
Revaccinate annually.

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 (50 doses)
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 multi-dose 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.

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

In addition to the adverse reactions observed after single dose vaccination, a mild swelling of the local lymph nodes may be observed within the first 3 days after administration of a ten-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Leporidae*, live viral vaccine for rabbits
ATCvet code: QI08AD

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 viruses.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Hydrolysed gelatine
Pancreatic digest of casein
Sorbitol
Disodium phosphate dihydrate

Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product (lyophilisate) as packaged for sale: 2 years.
Shelf life of the solvent as packaged for sale: 4 years.
Shelf life after reconstitution according to directions: 4 hours.

6.4 Special precautions for storage

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

Solvent:
No special precautions for storage.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I clear glass vial of 1 or 50 doses closed with a chlorobutyl rubber stopper and aluminium cap.

Solvent:
Type I clear glass vial of 0.5 ml or 10 ml closed with a bromobutyl rubber stopper and aluminium cap.

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

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5050

9. DATE OF FIRST AUTHORISATION

05 December 2019

10. DATE OF REVISION OF THE TEXT

October 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be

prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Approved 12 October 2022