SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROVAX RHD suspension for injection for rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) contains:

Active substances:

Rabbit haemorrhagic disease virus 1 (RHDV1) VP1a* ≥1 RP**
Rabbit haemorrhagic disease virus type 2 (RHDV2) VP1ab* ≥1 RP**

* recombinant capsid protein
** Relative potency: ELISA by comparison with a reference serum

Adjuvant:
Aluminium hydroxide (as Al^{3+}) 0.83 mg

Excipients:
Thiomersal 0.05 mg

For the full list of excipients, see section 6.1.

RP*: Relative potency (ELISA test) by comparison with a reference serum

3. PHARMACEUTICAL FORM

Suspension for injection
Whitish aqueous suspension with soft white sedimentation.

4. CLINICAL PARTICULARS

4.1 Target species

Rabbits, including pet (dwarf) rabbits

4.2 Indications for use, specyfing the target species

For active immunisation of rabbits from the age of 28 days to reduce mortality, infection, clinical signs and organ lesions of Rabbit Haemorrhagic Disease caused by RHDV and RHDV2.

Onset of immunity: 1 week
Duration of immunity: 1 year

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Low levels of maternally derived antibodies against RHD virus do not interfere with vaccine efficacy. However, no information is available on the use of the vaccine in animals with high levels of maternally derived antibodies. Thus, in situations where a high level of maternally derived antibodies against RHD virus is expected, the vaccination scheme must be adjusted accordingly.

4.5 Special precautions for use

Special precautions for use in animals
Pregnant does should be handled with special care to avoid stress and risk of abortion.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A small painless palpable nodule (maximum 5.2 mm diameter) may be very commonly observed at the injection site, resolving within 12 days.

A transient temperature increase up to 1.65 °C can very commonly occur in the first week following vaccination.

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

Can be used during pregnancy.

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.

Vaccination schedule: Administer one dose from 28-30 days of age onward.

Revaccinate every 12 months.

Vaccination using the single dose presentation (0.5 ml)
The pre-filled glass syringes needs to be attached to the needle included in the package. Administer one dose by subcutaneous injection.

Vaccination using multidose presentations (50 doses (25 ml) or 200 doses (100 ml))
The elastomer stoppers of the polypropylene bottles need to be punctured with a needle (attached to a syringe) to extract the appropriate volume for vaccination (0.5 ml per animal). Administer one dose by subcutaneous injection.

Before use allow the vaccine to reach room temperature.
Shake well before use to resuspend the sedimentation

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

No different local reactions were observed other than those described in section 4.6.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: IMMUNOLOGICALS FOR LEPORIDAE, Rabbit, inactivated viral vaccines, rabbit haemorrhagic disease virus
ATCVet Code: QI08AA01

To stimulate active immunity against RHDV (classical strain) and RHDV2 (new variant)
The active substances of the vaccine are two recombinant proteins: Rabbit Haemorrhagic Disease Virus VP1a (capsid protein VP1 and VP2 of strain Ast89) and Rabbit Haemorrhagic Disease Virus 2 VP1ab (chimera of strains Ast89 and N11), that auto-assemble into Virus-Like Particles (VLPs).

6. PHARMACUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dodecahydrate
Sodium chloride
Water for injection

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year
Shelf life after first opening the immediate packaging:10 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of the immediate packaging

Multidose presentations: Polypropylene bottles of 25 or 100 ml containing 50 or 200 doses with elastomer stopper Type I and aluminium cap.
Single dose presentation: Type I glass syringes of 0.5 ml containing a single dose with elastomer stopper. Needles provided with the syringes are sterile disposable pyrogen free and non-toxic needles 22Gx1¼'' (class IIA - Directive 93/42/EC as amended), CE marked and complying with EU Medical device Directive 93/42/EEC, ISO 9001, ISO 13485. Each needle with its protective cover is supplied inside an individual “peel-open” blister.

Pack sizes:
Paperboard box of 5 pre-filled syringes of 1 dose (5 x 0.5 ml) with sterile disposable needles for each in a protective cover.
Cardboard box of 1 polypropylene bottle of 50 doses
Cardboard box of 1 polypropylene bottle of 200 doses

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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40064 Ozzano dell'Emilia (BO)
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8. MARKETING AUTHORISATION NUMBER

Vm 11557/5000

9. DATE OF FIRST AUTHORISATION

21 September 2021

10. DATE OF REVISION OF THE TEXT

September 2021

Approved 21 September 2021