ANNEX I

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 2 (RHDV2) VP1ab* ≥1 RP**

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

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

Excipients:
Thiomersal 0.05 mg

For the full list of excipients, see section 6.1.

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 RHDV1 and RHDV2.

Onset of immunity: 1 week (7 days) after vaccination.

Duration of immunity: 1 year.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
The possible interference of MDAs cannot be excluded at the recommended age for vaccination.

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.
The safety of reproductive performance in male rabbits was not evaluated.

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 very small transient nodule (maximum 5.2 mm diameter) at the site of injection may commonly be visible or palpable in the first week post vaccination, in laboratory trials. In the repeated dose laboratory trials, upon necropsy small nodules in the subcutis at the injection site were commonly observed.

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 the first dose (0.5 ml) at 28 days of age.
Revaccination: 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 packaging. Administer one dose by subcutaneous injection.

Vaccination using multi-dose 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 sediment.

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

In dwarf rabbits, small transient nodules at the injection site were commonly noted after administration of a 2X dose that completely disappeared in the first two weeks.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for rabbits, inactivated viral vaccines, rabbit haemorrhagic disease virus.
ATCVet Code: QI08AA01.

To stimulate active immunity against RHDV1 (classical strain) and RHDV2 (new variant).
The active substances of the vaccine are two recombinant proteins: rabbit haemorrhagic disease virus 1 VP1a (capsid protein VP1 and VP2 of strain Ast89) and rabbit haemorrhagic disease virus 2 VP1ab (chimera of strains Ast89 and N11), which 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 injections

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: 9 months.
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

Multi-dose 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 and sterile disposable needles.

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

FATRO S.p.A.
Via Emilia 285
40064 Ozzano dell'Emilia (BO)
ITALY
E-mail: fatro@fatro.it

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/21/275/001-003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:16/08/2021

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substances and of the manufacturer responsible for batch release

FATRO S.p.A.
Via Emilia 285
40064 Ozzano dell'Emilia (BO)
Italy

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substances, being principles of biological origin intended to produce active immunity, are not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

25 ml bottle (50 doses), 100 ml bottle (200 doses) and 5 x 0.5 ml pre-filled syringes (5x1 dose) cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROVAX RHD suspension for injection for rabbits

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.5 ml) contains:

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

* recombinant capsid protein
** Relative potency: ELISA test by comparison with a reference serum in vaccinated mice

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

25 ml (50 doses)
100 ml (200 doses)
5 x 0.5 ml (5 x 1 dose)

5. TARGET SPECIES

Rabbit, including pet (dwarf) rabbits

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only. 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

FATRO S.p.A.
Via Emilia 285
40064 Ozzano dell'Emilia (BO)
ITALY
E-mail: fatro@fatro.it

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/21/275/001 5 x 1 dose
EU/2/21/275/002 50 doses

EU/2/21/275/003 200 doses

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROVAX RHD suspension for injection for rabbits

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.5 ml) contains:

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

* recombinant capsid protein
** Relative potency: ELISA test by comparison with a reference serum in vaccinated mice

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml (200 doses)

5. TARGET SPECIES

Rabbit

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Dose: 0.5 ml by subcutaneous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {MM/YYYY}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

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

For animal treatment only. To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A.
Via Emilia 285
40064 Ozzano dell'Emilia (BO)
ITALY
E-mail: fatro@fatro.it

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/21/275/003

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

25 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROVAX RHD suspension for injection for rabbits

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (0.5 ml) contains:
Rabbit haemorrhagic disease virus 1 (RHDV1) VP1a ≥1 RP
Rabbit haemorrhagic disease virus 2 (RHDV2) VP1ab ≥1 RP

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 doses

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

0.5 ml pre-filled syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROVAX RHD suspension for injection for rabbits

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (0.5 ml) contains:

RHDV1 VP1a ≥1 RP
RHDV2 VP1ab ≥1 RP

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose.

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

FATROVAX RHD suspension for injection for rabbits

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

Marketing authorisation holder and manufacturer responsible for batch release:

FATRO S.p.A., Via Emilia 285, 40064 Ozzano dell'Emilia (BO), ITALY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROVAX RHD suspension for injection for rabbits

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

Each dose (0.5 ml) contains:

Active substances:
Rabbit haemorrhagic disease virus 1 (RHDV1) VP1a* ≥1 RP**
Rabbit haemorrhagic disease virus 2 (RHDV2) VP1ab* ≥1 RP**

* recombinant capsid protein
** Relative potency: ELISA test by comparison with a reference serum in vaccinated mice

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

Preservative:
Thiomersal

Whitish aqueous suspension with soft white sedimentation easily resuspendable.

4. INDICATION(S)

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 RHDV1 and RHDV2.

Onset of immunity: 1 week (7 days) after vaccination.
Duration of immunity: 1 year.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A very small transient nodule at the site of injection may commonly be visible or palpable in the first week post vaccination in laboratory trials. In the repeated dose laboratory trials, upon necropsy small nodules in the subcutis at the injection site were commonly observed.

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)

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 inform your veterinary surgeon.

7. TARGET SPECIES

Rabbits, including pet (dwarf) rabbits

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

0.5 ml by subcutaneous route.

Vaccination programme:
Administer the first dose at 28 days of age; 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 packaging. Administer one dose by subcutaneous injection.

Vaccination using multi-dose 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.

9. ADVICE ON CORRECT ADMINISTRATION

Before use allow the product to reach room temperature.
Shake well before use to resuspend the sediment.

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 - 8 °C).
Do not freeze.

Protect from light.

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

Shelf life after first opening the immediate packaging: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.
The possible interference of MDAs cannot be excluded at the recommended age for vaccination.

Special precautions for use in animals:
Pregnant does should be handled with special care to avoid stress and risk of abortion.
The effect on reproductive performance in male rabbits was not evaluated.

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.

Use during pregnancy, lactation or lay:
Can be used during pregnancy.

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 dwarf rabbits, small transient nodules at the injection site were commonly noted after administration of a 2X dose.

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

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

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 (25 ml)
Cardboard box of 1 polypropylene bottle of 200 doses (100 ml)

Not all pack sizes may be marketed.

Immunological properties:
To stimulate active immunity against RHDV1 (classical strain) and RHDV2 (new variant).
The active substances of the vaccine are two recombinant proteins: rabbit haemorrhagic disease virus 1 VP1a (capsid protein VP1 and VP2 of strain Ast89) and rabbit haemorrhagic disease virus 2 VP1ab (chimera of strains Ast89 and N11), which auto-assemble into virus-like particles (VLPs).