ANNEX II

A. <MANUFACTURER<S> OF THE BIOLOGICAL ACTIVE SUBSTANCE<S> AND> MANUFACTURER<S> RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION>

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

Name and address of the manufacturer of the biological active substance 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.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Not applicable.

E. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Not applicable.

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 0.5ml 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

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) and 5 needles

5. TARGET SPECIES

Rabbit

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

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.

12. SPECIAL 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)

50 doses, 200 doses, 5 x 1 dose
Vm 11557/5000

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

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.

12. SPECIAL 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)

Vm 11557/5000

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 (0.5ml) 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 (0.5ml) 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

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 INGREDIENT(S)

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

Adjuvant:
Aluminium hydroxide

Preservative:
Thiomersal

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

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 symptoms and organ lesions of Rabbit Haemorrhagic Disease caused by RHDV and RHDV2.

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

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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)

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 one dose from 28-30 days of age onward; revaccinate every 12 months.

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

<u>Vaccination using multidose presentations (50 doses (25 ml) or 200 doses (100 ml))</u>
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 sedimentation.

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.
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 (one working day)

12. SPECIAL WARNING(S)

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 .

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.

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.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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.

Approved 21 September 2021