ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V -SUSPENSION FOR INJECTION FOR RABBIT S~~uspension for injection for rabbits~~.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) of vaccine contains:

Active substances:
Rabbit h~~H~~aemorrhagic d~~D~~isease v~~V~~irus strain LP.SV.2012 (variant strain 2010, RHDV2), inactivated……..min 1 PD90% *

Rabbit h~~H~~aemorrhagic d~~D~~isease v~~V~~irus strain IM507.SC.2011 (classical strain, RHDV1), inactivated……..min 1 PD90% *

Adjuvant:
Aluminium hydroxide ~~($Al(OH)_3$)~~ ……0.35 mg

(*) Protective dose in at least 90% of the vaccinated animals.

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Reddish homogeneous suspension.

4. CLINICAL PARTICULARS

4.1. Target species

Rabbits~~.~~

4.2. Indications for use, specifying the target species

For active immunisation of rabbits from 10 weeks of age, to reduce mortality due to rabbit haemorrhagic disease caused by classical (RHDV1) and type 2 (RHDV2) virus strains.

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

4.3. Contraindications

None.

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4.4. Special warnings for each target species

Vaccinate healthy animals only.

No information is available on the use of the vaccine in seropositive animals, including animals with maternally derived antibodies. Thus, in situations where a high level of antibodies is expected, the vaccination scheme must be adjusted accordingly.
The efficacy of the vaccine in animals younger than 10 weeks of age has not been demonstrated.

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

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 temporary increase in body temperature of up to 1.6°C has been observed very commonly one day after vaccination in clinical studies.
A limited local reaction (subcutaneous nodule, the size of which was up to 10 mm in diameter in the double dose study) which may be palpable for at least 52 days and which disappears without treatment has been observed very commonly in clinical studies.
Serious hypersensitivity reactions which may be fatal have been reported very rarely from post marketing pharmacovigilance reporting ~~safety experience~~.

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:
During a field trial, no case of abortion was noted after administration of the vaccine to pregnant animals.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
The influence of the vaccination on the fertility of rabbits has not been investigated.

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.

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4.9. Amounts to be administered and administration route

Subcutaneous use.
One dose (0.5 ml) per subcutaneous injection per animal.
Primary vaccination: from the 10th week of age.
Revaccination: annually.

Apply usual aseptic conditions.
Shake gently before and occasionally during administration to maintain a homogeneous suspension.

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

No adverse reactions other than those referenced in section 4.6 have been observed after administration of a double dose of the vaccine.

4.11. Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, inactivated viral vaccine for rabbits, Rabbit Haemorrhagic Disease Virus (RHDV)
ATC vet code: QI08AA01
The vaccine is intended to stimulate active immunity against Rabbit Haemorrhagic Disease Virus (RHDV) caused by RHDV1 (classical form) and RHDV2 (variant form).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Aluminium hydroxide
Sodium metabisulphite ~~disulfite~~
Disodium ~~hydrogen~~ phosphate dihydrate
Potassium dihydrogen phosphate
Sodium hydroxide
Water for injections

6.2. Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 2 hours.

6.4. Special precautions for storage

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

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6.5. Nature and composition of immediate packaging

Type I glass bottles closed with nitrile rubber stoppers and aluminium caps.

50 doses: 1 vial with 25 ml vaccine.
10 vials with 25 ml vaccine.
200 doses: 1 vial with 100 ml vaccine.
10 vials with 100 ml vaccine.

Secondary packaging: cardboard box.

Single-dose: 1 vial with 0.5 ml vaccine.
5 vials with 0.5 ml vaccine.
10 vials with 0.5 ml vaccine.

Secondary packaging: plastic blister.

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 veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

FILAVIE
20, La Corbière ROUSSAY
49450 Sèvremoine
FRANCE
Tel.: +33 2 41 75 46 16
Fax: + 33 2 41 75 75 80
E-mail: contact.filavie@filavie.com

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY
Date of last renewal: DD/MM/YYYY

10. DATE OF REVISION OF THE TEXT

DD/MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

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ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 1 or 10 glass vials (25 ml vaccine = 50-dose presentation and 100 ml vaccine = 200-dose presentation)
Plastic blister with 1, 5 or 10 glass vials (0.5 ml vaccine = 1-dose presentation)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V suspension for injection for rabbits.

2. STATEMENT OF ACTIVE SUBSTANCES

Rabbit ~~H~~haemorrhagic ~~D~~disease ~~V~~virus strain LP.SV.2012 (variant strain 2010, RHDV2), inactivated……min 1 PD90% *
Rabbit ~~H~~haemorrhagic ~~D~~disease ~~V~~virus strain IM507.SC.2011 (classical strain RHDV1), inactivated……min 1 PD90% *

(*) Protective dose in at least 90% of the vaccinated animals

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

Single-dose: 1 x 0.5 ml vaccine
5 x 0.5 ml vaccine
10 x 0.5 ml vaccine

50 doses: 1 x 25 ml vaccine
10 x 25 ml vaccine

200 doses: 1 x 100 ml vaccine
10 x 100 ml vaccine

5. TARGET SPECIES

Rabbits.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read the package leaflet.

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

FILAVIE
20, La Corbière ROUSSAY
49450 Sèvremoine
FRANCE
Tel.: +33 2 41 75 46 16
Fax: + 33 2 41 75 75 80
E-mail: contact.filavie@filavie.com

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VACCINE GLASS VIAL LABEL (1, 50 and 200 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V suspension for injection for rabbits.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Rabbit h~~H~~aemorrhagic d~~D~~isease v~~V~~irus strain LP.SV.2012 (variant strain 2010, RHDV2), inactivated……min 1 PD90% *
Rabbit h~~H~~aemorrhagic d~~D~~isease v~~V~~irus strain IM507.SC.2011 (classical strain RHDV1), inactivated……min 1 PD90% *

(*) Protective dose in at least 90% of the vaccinated animals

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

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

4. ROUTE(S) OF ADMINISTRATION

SC.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 2 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET ~~FOR:~~
FILAVAC VHD K C+V 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:
FILAVIE
20, La Corbière ROUSSAY
49450 Sèvremoine
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V suspension for injection for rabbits.

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

Each dose of vaccine (0.5 ml) contains:

Active substances:
Rabbit h~~H~~aemorrhagic d~~D~~isease ~~V~~v irus strain LP.SV.2012 (variant strain 2010, RHDV2), inactivated……min 1 PD90% *
Rabbit ~~H~~haemorrhagic d~~D~~isease v~~V~~irus strain IM507.SC.2011 (classical strain RHDV1), inactivated……min 1 PD90% *

Adjuvant:
Aluminium hydroxide ~~(Al(OH)$_3$)~~: ……0.35 mg

(*) Protective dose in at least 90% of the vaccinated animals.

Suspension for injection.
Reddish homogeneous suspension.

4. INDICATIONS

For active immunisation of rabbits from 10 weeks of age, to reduce mortality due to rabbit haemorrhagic disease caused by classical (RHDV1) and type 2 (RHDV2) virus strains.

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A temporary increase in body temperature of up to 1.6°C has been observed very commonly one day after vaccination in clinical studies.
A limited local reaction (subcutaneous nodule, the size of which was up to 10 mm in diameter in the double dose study) which may be palpable for at least 52 days and which disappears without treatment has been observed very commonly in clinical studies.
Serious hypersensitivity reactions which may be fatal have been reported very rarely from post marketing pharmacovigilance reporting~~safety experience~~.
Lethargy and/or inappetence have been reported very rarely in the first 48 hours after injection, from post marketing pharmacovigilance reporting.

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.

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

Subcutaneous use.
One dose (0.5 ml) per subcutaneous injection per animal.

Primary vaccination: from the 10th week of age.
Revaccination: annually.

9. ADVICE ON CORRECT ADMINISTRATION

Apply usual aseptic conditions.
Shake gently before and occasionally during administration to maintain a homogeneous suspension.

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 label.

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: 2 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.
No information is available on the use of the vaccine in seropositive animals, including animals with maternally derived antibodies. Thus, in situations where a high level of antibodies is expected, the vaccination scheme must be adjusted accordingly.
The efficacy of the vaccine in animals younger than 10 weeks of age has not been demonstrated.

Special precautions for use in animals:
Not applicable.

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.
This product contains aluminium hydroxide. An accidental self-injection by the person administering the vaccine may result in a local inflammatory reaction, with more or less severe pain at the injection site (in particular if injected into a finger).
Accidental injection to humans may result in bacterial infection.

As soon as possible after the accidental (self-) injection, you must:
- Clean and disinfect the injection site.
- Put ice on the zone of injection.
- Seek prompt medical advice and take the package (vial, label and leaflet) insert with you.

Pregnancy:
During a field trial, no case of abortion was noted after administration of the vaccine to pregnant animals. .
Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
The influence of the vaccination on the fertility of rabbits has not been investigated.

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):
No adverse reactions other than those referenced in section 6 have been observed after administration of a double dose of vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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 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

DD/MM/YYYY

15. OTHER INFORMATION

50 doses:	1 vial with 25 ml vaccine. 10 vials with 25 ml vaccine.
200 doses:	1 vial with 100 ml vaccine. 10 vials with 100 ml vaccine.

Secondary packaging: cardboard box.

Single-dose:	1 vial with 0.5 ml vaccine. 5 vials with 0.5 ml vaccine. 10 vials with 0.5 ml vaccine.

Secondary packaging: plastic blister.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

FILAVIE
20, La Corbière ROUSSAY
49450 Sèvremoine
FRANCE
Tel.: +33 2 41 75 46 16
Fax: +33 2 41 75 75 80
E-mail: contact.filavie@filavie.com