SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V suspension for injection for rabbits (1-dose).
FILAVAC VHD K C+V concentrate and solvent for suspension for injection for rabbits (50-dose and 200-dose presentations).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

0.5 ml dose of vaccine for single-dose presentation or 0.2 ml for the 50-dose and 200-dose presentations contains:

Rabbit Haemorrhagic Disease Virus strain LP.SV.2012 (variant strain 2010, RHDV2), inactivated…….min 1 PD90% *

Rabbit Haemorrhagic Disease Virus strainIM507.SC.2011 (classical strain, RHDV1), inactivated……..…….min 1 PD90% *

Adjuvant:
Aluminium hydroxide (Al^{3+}) ……..……0.35 mg

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection (1-dose).
Concentrate and solvent for suspension for injection (50-dose and 200-dose presentations).
Reddish homogeneous suspension before and after dilution.

4. CLINICAL PARTICULARS

4.1. Target species

Rabbits.

4.2. Indications for use, specifying the target species

For active immunisation of rabbits (fattening and future breeders) 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: 7 days.
Duration of immunity: 12 months.

4.3. Contraindications

None.

4.4. Special warning

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.
No information is available on the safety and efficacy in pet rabbits.

4.5. Special precautions for use

i) Special precautions for use in animals

Vaccinate only healthy rabbits.

ii) 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)

Very common: a temporary increase in body temperature of up to 1.6°C can be observed one day after vaccination.
Common: Immunization is followed by a limited local reaction (subcutaneous nodule up to 3 mm in diameter) which may be palpable and observable for at least 52 days.

The frequency of adverse reactions is defined using the following convention:

-very common (more than 1 in 10 animals occurring adverse reactions during the course of one treatment);
-common (more than 1 but less than 10 animals in 100 animals);
-uncommon (more than 1 but less than 10 animals in 1,000 animals);
-rare (more than 1 but less than 10 animals in 10,000 animals);
-very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7. Use during pregnancy and lactation

Pregnancy:
The available study (field trial) has not shown abortion in 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.

4.9. Amounts to be administered and administration route

One dose per subcutaneous injection to each animal with a volume of 0.5 ml for the single-dose presentation or 0.2 ml for the 50-dose and 200-dose presentations.

First vaccination from the 10th week of age.
Re-vaccination: annual

Dilution of the vaccine for 50-dose and 200-dose presentations:
Apply usual aseptic conditions.
Take the diluent in a sterile syringe with a sterile needle and inject the diluent into the vial of vaccine.
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 vaccine.

4.11. Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, inactivated viral vaccine for rabbits, Rabbit Haemorrhagic Disease Virus (RHDV)
ATCvet code: QI08AA01
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

Single-dose presentation:
Aluminium hydroxide
Sodium disulfite
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Sodium hydroxide
Water for injections

Multi-dose presentation:
Aluminium hydroxide
Sodium disulfite
Disodium phosphate dihydrate
Potassium dihydrogen phosphate

Sodium hydroxide
Water for injections

Diluent:
Water for injections

6.2. Incompatibilities

Do not mix with any other veterinary medicinal product, except the diluent supplied for use with the multi-dose veterinary medicinal product.

6.3. Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 14 months.
Shelf-life after dilution according to directions (only for multi-dose presentation): 2 hours.

6.4. Special precautions for storage

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

6.5. Nature and composition of immediate packaging

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

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.

50 doses: 1 vial with 7.5 ml vaccine and 1 vial with 2.5 ml diluent.
14 vials with 7.5 ml vaccine and 14 vials with 2.5 ml diluent.
200 doses: 1 vial with 30 ml vaccine and 1 vial with 10 ml diluent.
14 vials with 30 ml vaccine and 14 vials with 10 ml diluent.

Secondary packaging: cardboard box.

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

8. MARKETING AUTHORISATION NUMBER

Vm 46470/4000

9. DATE OF FIRST AUTHORISATION

24 April 2017

10. DATE OF REVISION OF THE TEXT

July 2017

Approved: 26 July 2017