SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V SUSPENSION FOR INJECTION FOR RABBITS.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) of vaccine contains:

Active substances:
Rabbit haemorrhagic disease virus strain LP.SV.2012 (variant strain 2010, RHDV2), inactivated…….min 1 PD90% *

Rabbit haemorrhagic disease virus strain IM507.SC.2011 (classical strain, RHDV1), inactivated…….min 1 PD90% *

Adjuvant:
Aluminium hydroxide ……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.

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.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).

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.

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
Disodium 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.

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 Corbiere - Roussay
49450 Sevremoine
France

8. MARKETING AUTHORISATION NUMBER

Vm 46470/4000

9. DATE OF FIRST AUTHORISATION

24 April 2017

10. DATE OF REVISION OF THE TEXT

October 2020

Approved 30 October 2020