SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FILAVAC VHD K C+V

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

RDH virus strain LP.SV.2012 (variant 2010, RHDV2) ……..min 1 PD90% *

RDH virus strain IM507.SC.2011……..min 1 PD90% *

Excipient(s) :
Aluminium (hydroxyde form) : ……0,35 mg
Excipients QSP 1 dose

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

For a full list of excipients, see section « List of excipients ».

3. PHARMACEUTICAL FORM

Reddish homogeneous suspension after reconstitution.

4. CLINICAL PARTICULARS

4.1. Target species

Rabbit.

4.2. Indications for use, specifying the target species

For active immunisation of future breeders rabbits from 10 weeks of age, and breeders, onwards to prevent mortality due to rabbit haemorrhagic disease caused by classical and « variant » RHD virus strains.
Onset of immunity: 7 days.
Duration of immunity: 17 months.

4.3. Contraindications

None.

4.4. Special warning

No information available on the use of the vaccine in seropositive animals, including animals with maternally derived antibodies. Thus, in situations where it is expected a high level of antibodies, the immunisation protocol must be designed accordingly.

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 injection of the vaccine to humans, a medical consultation is required.

iii) Other precautions

None.

4.6. Adverse reactions (frequency and seriousness)

Immunization is followed by a limited local reaction (subcutaneous nodule up to 3 mm in diameter) may be palpable for at least 52 days.

4.7. Use during pregnancy and lactation

The available studies (field trial) have not shown abortion in pregnant animals. However, pregnant females should be handled with the usual precautions.

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

Administer by subcutaneous injection to each animal a dose of 0.2 ml for the 50 doses and 200 doses presentations or 0.5 ml for the 1 dose presentation.

- Common vaccination program in rabbit breeders

  - Primo vaccination from the 10th of age
  - Booster every 6-12 months, according to the sanitary situation of the farm and according to the conditions of vaccine administration applied in the farm.

- Vaccination program adviced according the epidemiological situation and in particular if any risks of contamination before the age of 10 weeks:

  - Possible to proceed a first injection from 4 weeks of age
  - In future rabbit breeders, it is advised to complete the first injection with a second injection at 10 weeks of age
  - Booster every 6-12 months, according to the sanitary situation of the farm and according to the conditions of vaccine administration applied in the farm.

Reconstitution of the vaccine for presentations 50 doses and 200 doses:
Apply usual aseptic conditions.
Take the solvent in a syringe and inject the solvent into the vial of vaccine.
Shake before and occasionally during administration.

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

No adverse reactions other than those referred in section "adverse reactions" have been observed after administration of a double dose of vaccine.

4.11. Withdrawal period(s)

Zero days.

5. Immunological properties

ATC Vet Code : QI08AA01
To stimulate immunity against rabbit haemorrhagic disease virus variant form and traditional form.

6. Pharmaceutical particulars

6.1. List of excipients

Aluminium Hydroxyde
Sodium disulfite
Phosphate buffer
Water for injections

6.2. Incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the vaccine.

6.3. Shelf life

Shelf-life of the vaccine as packaged for sale: 14 months.
Shelf-life after reconstitution: 2 hours.

6.4. Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Protect from light.

6.5. Nature and composition of immediate packaging

Type I glass bottle
Nitrile rubber stopper
Aluminium cap

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

The empty packaging and any remaining product should be disposed following the practices governed by regulations on waste.

7. MARKETING AUTHORISATION HOLDER

FILAVIE
LA CORBIERE
49450 ROUSSAY

8. MARKETING AUTHORISATION NUMBER(S)

FR/V/1386663 7/2015

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/09/2015

10. DATE OF REVISION OF THE TEXT

29/09/2015