

PACKAGE LEAFLET

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UK, IE: Anivac VHD

ES, PT: CALICIVAC

CZ, DE, HU, PL, FR: CASTOREX

Suspension for injection for rabbits

1. Name and address of the manufacturing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Pharmagal Bio, s. r. o.,
Murgašova 5
949 01 Nitra
Slovak Republic

2. Name of the veterinary medicinal product

UK, IE: Anivac VHD

ES, PT: CALICIVAC

CZ, DE, HU, PL, FR: CASTOREX

Suspension for injection for rabbits

3. Statement of the active substance(s) and other ingredient(s)

One dose of vaccine (0.5 ml) contains:

Active substances:

Inactivated Rabbit Haemorrhagic Disease Virus strain RHDV PHB98.....min. 1 PD₉₀*

Adjuvant :

Aluminium hydroxide gel 1.3 mg

Excipients:

Formaldehyde 0.55 mg

Thiomersal 0.05 mg

* Protective dose for minimum 90% of vaccinated animals

4. Indication(s)

Active immunisation against haemorrhagic disease.

For active immunisation of rabbits to prevent mortality caused by RHD virus

Onset of immunity: 7 days

Duration of immunity: 1 year based on field data without controlled challenge

5. Contra-indications

Do not vaccinate animals sick or suspected from any disease.

6. Adverse reactions

In laboratory studies in dwarf rabbits vaccinated with double dose a small swelling of approximately 5mm that disappeared up to 3 days was observed.

The effects of a double dose in pregnant rabbits have not been investigated.

If you notice any serious effects or other effects not mentioned in this leaflet please inform your veterinary surgeon.

7. Target species

Rabbit

8. Dosage for each species, route(s) and method of administration

The vaccine dose for all age categories is 0.5 ml.

1 dose of 0.5 ml per rabbit, administered subcutaneously, it is recommended to localise the site of administration to the lateral thoracic wall.

Primary vaccination: 1 injection in rabbits from the age of 10 weeks.

Booster: 1 injection every 12 months.

With respect to the epizootological situation, it is possible to vaccinate rabbits younger than 10 weeks (but not earlier than at the age of six weeks) with subsequent revaccination 4 weeks after the first vaccination.

9. Advice on correct administration

Shake well before and occasionally during administration.

10. Withdrawal period

Zero days.

11. Special storage precautions

Keep out of the reach and sight of children.

Store in a refrigerator (2 °C – 8 °C). Protect from frost.

Once opened, store below 25°C.

Shelf-life after first opening the immediate packaging: 10 hours.

Do not use after the expiry date which is stated on the label.

12. Special warnings

Do not mix with any other veterinary medicinal product.

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.

Can be used during pregnancy and lactation.

It is recommended not to vaccinate in the later stages of pregnancy in order to avoid stress and handling of pregnant does.

No information is available on the use of the vaccine in seropositive animals including those with maternally derived antibodies; therefore in situations where high antibody levels are expected the vaccination protocol should be planned accordingly.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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 of the last update

15. Other information

Size of package

Vials with the content of 10 doses (5 ml), 20 doses (10 ml), 40 doses (20 ml),

10 x 1 dose (10 x 0.5 ml)

Keep the container in outer carton.

Not all package sizes will be marketed.

For animal treatment only.

Available by prescription only.