SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the immunological veterinary medicinal product

UK, IE: Anivac VHD

CZ, DE, HU, PL, FR: CASTOREX

ES, PT: CALICIVAC

Suspension for injection for rabbits

2. Qualitative and quantitative composition

One dose of vaccine (0.5 ml) contains:

Active substances:

Inactivated Rabbit Haemorrhagic Disease Virus strain RHDV PHB98 …… min. 1 PD_{90} *

Adjuvant:

Aluminium hydroxide gel ..... 1.3 mg

Excipients:

Formaldehyde …… 0.55 mg

Thiomersal …… 0.05 mg

Excipient …… qsp 0,5 ml

For a full list of excipients, see section 6.1.

*** Protective dose for minimum 90% of vaccinated animals**

3. Pharmaceutical form

Suspension for injection.
Suspension of red-brown colour with easily shakeable sediment of inactivated RHDV adsorbed on aluminium hydroxide gel that forms 40-60% of the vaccine if left undisturbed.

4. Clinical particulars

4.1. Target species

Rabbit.

4.2. Indications for use, specifying the target species

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

4.3. Contra-indications

Do not vaccinate animals sick or suspected from any disease.

4.4. Special warnings for each target species

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.

4.5. Special precautions for use

Special precautions for use in animals

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

Special precautions to be taken by the person administering the 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.

Other precautions

None.

4.6. Adverse reactions (frequency and seriousness)

None.

4.7. Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

See section 4.5

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

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.

Shake well before and occasionally during administration.

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

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.

4.11. Withdrawal periods

Zero days.

5. Immunological properties

ATCvet.: QI 08 AA 01

To stimulate active immunity against rabbit haemorrhagic disease.

6. Pharmaceutical particulars

6.1. List of excipients:

Formaldehyde

Thiomersal

Phosphate buffered solution (PBS)

6.2. Incompatibilities

Do not mix with any other veterinary medicinal products.

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

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Protect from frost.
Once opened, store below 25°C.

6.5. Nature and composition of immediate packaging

Glass vials made of neutral borosilicate glass with high hydrolytic resistance (Type 1) closed with a rubber plug suitable for parenteral preparations and an aluminium cap.

Size of package:
10 x 1 dose (10 x 0.5 ml)
10 doses (5 ml) in one vial
20 doses (10 ml) in one vial
40 doses (20 ml) in one vial

Not all pack sizes will be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal products 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

PHARMAGAL BIO, s. r. o.
Murgašova 5
949 01 Nitra
Slovak Republic

8. Marketing authorisation number

Czech Republic	97/030/00-C
Germany	PEI.V.03397.01.1
Hungary	2209/1/07 MgSzH ÁTI (10adag) 2209/2/07 MgSzH ÁTI (20 agad) 2209/3/07 MgSzH ÁTI (40 adag)
Poland	1770/07
Spain	1780 ESP
Portugal	AIM no 782/07RIVPT
France	FR/V/8993419 1/2008
United Kingdom	Vm 33225/4000
Ireland	VPA 10556/001/001
Slovak Republic	97/119/99-S

9. Date of first authorisation / Renewal of the authorisation

Date of first authorisation:
Slovak Republic on October 26, 1999
Czech Republic on April 7, 2000
Germany on December 12, 2006
Hungary on June 11, 2007
Poland on August 13, 2007
Spain on October 5, 2007
Portugal on July 24, 2007
France on August 04, 2008
United Kingdom on October 17, 2008
Ireland on November 10, 2008

Renewal of the authorisation:
Slovak Republic in October 26, 2004
Czech Republic in April 7, 2005

10. Date of revision of the text