

LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{Paper box }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK, IE: Anivac VHD

CZ, DE, HU, PL, FR: CASTOREX

ES, PT: CALICIVAC

Suspension for injection for rabbits

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose 0.5 ml contains:

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

Aluminium hydroxide gel 1.3 mg

Formaldehyde

Thiomersal

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

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

5 ml / 10 doses (10 ml / 20 doses, 20 ml / 40 doses)
10 x 0.5 ml / 10 x 1 dose

5. TARGET SPECIES

Rabbit.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use. Administer the injection preferably to the lateral thoracic wall.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

Once opened , use within 10 hours.

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

11. SPECIAL STORAGE CONDITIONS

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

Once opened, store below 25°C.

Read the package leaflet before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only!
To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot><BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Glass vial for 10,20,40 doses }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK, IE: Anivac VHD

CZ, DE, HU, PL, FR: CASTOREX

ES, PT: CALICIVAC

Suspension for injection for rabbits

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (0.5 ml) contains:

Inactivated Rabbit Haemorrhagic Disease Virus strain RHDV PHB98minimum 1 PD₉₀*

Aluminium hydroxide gel 1.30 mg

* Protective dose for minimum 90% of vaccinated animals

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml/ 10 doses (10 ml/ 20 doses, 20 ml/ 40 doses)

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

<Batch><Lot><BN> {number}

7. EXPIRY DATE

<EXP {month/year}>

Once opened, use within 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Glass vials for 1 dose }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK, IE: Anivac VHD

CZ, DE, HU, PL, FR: CASTOREX

ES, PT: CALICIVAC

Suspension for injection for rabbits

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**One dose (0.5 ml) contains:****Inactivated rabbit haemorrhagic disease virus strain RHDV PHB98 minimum 1 PD₉₀****Aluminium hydroxide gel 1.30 mg****3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES****0,5 ml/ 1 dose****4. ROUTE(S) OF ADMINISTRATION****Subcutaneous use****5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

6. BATCH NUMBER

<Batch><Lot><BN> {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.