PACKAGE LEAFLET

PACKAGE LEAFLET

Anivac VHD Suspension for injection

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

Anivac VHD 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 PD_{90}*

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

None.

6. Adverse reactions

None.
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 sight and reach 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 this veterinary medicinal product the expiry after date which is stated on the label.

12. Special warnings

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.

Special precautions for use in animals: Do not vaccinate unhealthy 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 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.

Use during pregnancy, lactation or lay: Can be used during pregnancy and lactation.

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.

Overdose (symptoms, emergency procedures, antidotes): 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.

Incompatibilities: Do not mix with any other veterinary medicinal products.

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 on which the package leaflet was last approved

15. Other information

Size of package
Paper carton containing glass vial 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.

To be supplied only on veterinary prescription.

LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
{Paper box }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anivac VHD 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 PD_{90}*
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)

Read the package leaflet before use.

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.

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 SIGHTAND REACH OF CHILDREN"

Keep out of the sight and reach 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)

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

Anivac VHD 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 PD_{90}*
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

Anivac VHD 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 PD_{90}
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.