B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

BioRabbit RHDV 1, 2 suspension for injection for rabbits

2. Composition

One dose (0.5 ml) contains:
Active substances:
Inactivated rabbit haemorrhagic disease virus, type 1a (RHDV a), strain Bio 89 min. 60*

Inactivated rabbit haemorrhagic disease virus, type 2 (RHDV 2), strain Bio 88 min. 80*

*Titre of haemagglutination inhibition antibodies after application of the vaccine to laboratory animals (rabbits)

Adjuvant:
Aluminum hydroxide 2.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.05 mg

The liquid of white to grey-white colour with the presence of fine sediment. On prolonged standing, the contents split into a clear liquid and a milky white to grey-white sediment, which dispersed homogeneously after shaking.

3. Target species

Rabbits.

4. Indications for use

For active immunization of rabbits from the age of 6 weeks to prevent mortality caused by rabbit haemorrhagic disease virus type RHDV/RHDVa and type RHDV2.

Onset of immunity: 7 days after vaccination
Duration of immunity: 12 months

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Safety tests have not been performed on dwarf rabbits.

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.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy:
Can be used during pregnancy.
The use is not recommended for rabbit in the last week of pregnancy due to the possibility of abortion by careless fixation.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with the Bioveta's vaccine with live myxomatosis virus in Member States where this vaccine is authorized.

For mixed use, an onset of immunity of 7 days and duration of immunity of 6 months has been demonstrated for RHDV a and RHDV 2 components in rabbits from 8 weeks of age. When both vaccines are given at different sites, at the same time, an onset of immunity of 7 days has been demonstrated for RHDV a and RHDV 2 components in rabbits from 8 weeks of age, duration of immunity has not been demonstrated.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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:
Not applicable.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except with the vaccine recommended for use with the veterinary medicinal product mentioned in section Interaction with other medicinal products and other forms of interaction.

7. Adverse events

None.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}. See also section 16 for respective contact details.

8. Dosage for each species, routes and method of administration

Vaccination dose - one dose (0.5 ml) administered subcutaneously.
Animals can be vaccinated from 6 weeks of age.
Annual revaccinations are carried out no later than 12 months after the last vaccination.

When this vaccine is used to dilute Bioveta's vaccine with live myxomatosis virus, only a vaccine with the same number of doses can be combined and one dose is also 0.5 ml (i.e. for example: 10 doses of Bioveta's vaccine with live myxomatosis virus can be diluted with 10 doses of this vaccine). This is administered subcutaneously.

9. Advice on correct administration

Slowly warm up to room temperature and shake well before use.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Protect from frost.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 10 hours.
Shelf life after mixing BioRabbit RHDV 1, 2 with Bioveta's vaccine with live myxomatosis virus: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

The vaccine is presented:

in colourless glass vials hydrolytic class I:	3 ml vial containing 0.5 ml (1 dose)
	10 ml vial containing 5 ml (10 doses)
	10 ml vial containing 10 ml (20 dose)
in translucent plastic (HDPE) vials:	15 ml vial containing 5 ml (10 doses)
	15 ml vial containing 10 ml (20 doses)

The vials are closed with chlorobutyl rubber stoppers and aluminium caps or flip-off caps and placed in a paper or plastic box. Each package is accompanied by an approved package leaflet.

Pack sizes:

Cardboard box containing 1 x 10 doses or 1 x 20 doses.
Plastic box containing 10 x 1 dose, 10 x 10 doses or 10 x 20 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Bioveta, a.s.
Komenského 212/12
683 23 Ivanovice na Hané
Česká republika

<Local representatives< and contact details to report suspected adverse reactions>:>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

After administration to the rabbits the vaccine stimulates production of specific antibodies against type RHDV/RHDVa and RHDV2. Stimulation of immunity against RHDV is drawn from scientific reasoning.

possibility of multilingual packaging