

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

cardboard box: 1 x 10 doses, 1 x 20 doses

etiquette for plastic box: 10 x 1 doses, 10 x 10 doses, 10 x 20 doses

*possibility of multilingual packaging*

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

BioRabbit RHDV 1, 2 suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

One dose (0.5 ml) contains:

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\*

\*See package leaflet

**3. PACKAGE SIZE**

10 x 1 dose, 1 x 10 doses, 10 x 10 doses, 1 x 20 doses, 10 x 20 doses

**4. TARGET SPECIES**

Rabbits

**5. INDICATIONS**

Read the package leaflet before use.

**6. ROUTES OF ADMINISTRATION**

Subcutaneously route.

**7. WITHDRAWAL PERIODS**

Withdrawal periods: Zero days.

**8. EXPIRY DATE**

Exp {mm/yyyy}

Once broached use within 10 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated (2 °C–8 °C).

Protect from frost.

Protect from light.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

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

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Bioveta, a. s.

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

etiquette for glass vial: 3 ml (filled volume 0.5 ml)  
etiquette for glass vial: 10 ml (filled volume 5 ml or 10 ml)  
etiquette for plastic vial: 15 ml (filled volume 5 ml or 10 ml)

*possibility of multilingual packaging*

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

BioRabbit RHDV 1, 2 suspension for injection

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

One dose (0.5 ml) contains:

RHDV a

RHDV 2

**3. BATCH NUMBER**

Lot: {number}

**4. EXPIRY DATE**

Exp {mm/yyyy}