

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Text on cardboard box 20 pcs of baits
Text on cardboard box 30x20 pcs of baits
Text on plastic bags 30 pcs of baits
Text on cardboard box 700 pcs of baits (1 x 700 pcs or 2 x 350 pcs)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RABADROP, oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Composition 1 dose (1.8 ml):

Active substance:

Rabies virus SAD Clone attenuated 1.8x10^{6.0} TCID₅₀* – 1.8x10^{8.5} TCID₅₀*
Tissue culture infectious dose – 50%

Biomarker:

Tetracycline hydrochloride

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

20 pcs of baits
30 x 20 pcs of baits
30 pcs of baits
1 x 700 pcs of baits
2 x 350 pcs of baits

5. TARGET SPECIES

Red fox (*Vulpes vulpes*), raccoon dog (*Nyctereutes procyonoides*)

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store and transport frozen at the temperature -20 °C and lower

In case the vaccine is defrosted within its shelf life, however not later than 21st month of the shelf life, the vaccine can be stored and used for 90 days after defrosting when kept between +2°C and +8°C.

Do not refreeze.

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

Dispose of waste material in accordance with local requirements.

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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a.s., Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Text on PE sleeve - 1 x 700 pcs of baits, Text on PE bag - 350 pcs of baits

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RABADROP, oral suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Composition 1 dose (1.8 ml):

Active substance:

Rabies virus SAD Clone attenuated $1.8 \times 10^{6.0}$ TCID₅₀ – $1.8 \times 10^{8.5}$ TCID₅₀
Tissue culture infectious dose – 50%

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

1 x 700 pcs of baits

350 pcs of baits

4. ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Not applicable.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RABADROP

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a.s.,

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

6. LABELLING “ATTENTION: Rabies vaccine”

ATTENTION: Vaccine against rabies!