

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTBOARD/PLASTIC BOX

(10x1 ml, 25x1 ml, 50x1 ml or 1x10 ml and 10x10 ml presentations)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan Novel R, suspension for injection for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (1 ml):

Active substances:

Inactivated rabies virus, strain SAD Vnukovo-32 > 2.0 IU

Adjuvant

Aluminium hydroxide (quantified as Al₂O₃)

Excipients:

Thiomersal

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10x1 ml, 25x1 ml, 50x1 ml or 1x10 ml and 10x10 ml

5. TARGET SPECIES

Dogs.



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

Do not freeze.

Protect from light.

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 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

BN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING

UNITS (1 ml, 10 ml vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan Novel R, suspension for injection for dogs



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Rabies virus

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

1 dose, 10 doses

4. ROUTE(S) OF ADMINISTRATION

s.c.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.