BIOVETA, a. s. Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
tel.:420/517/363321-4 e-mail: comm@bioveta.cz

1B: SUMMARY OF PRODUCT CHARACTERISTICS

BIOVETA, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
e-mail: comm@bioveta.cz

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Biocan R suspension for injection
Inactivated vaccine against rabies

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition - 1 mL:
Active ingredient - *Virus rabiei* inactivatum, strain SAD Vnukovo-32 min. 2 IU
Excipients - Algedratum
- Thiomersalum

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target animal species

Dogs, cats, fur animals, cattle, horses, sheep, goats, pigs.

4.2 Indications with specification of the target animal species

For active immunisation of target animal species against rabies.

4.3 Contraindications

Systemic febrile disease. Non-vaccinated animals, injured or in contact with rabies-infected animals. Animals, which bit or injured a human, may be vaccinated only after the termination of an observation period.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only clinically healthy individuals in a proper nutritional condition. Possible anti-parasitic treatment should precede vaccination at least ten days. One week after the vaccination, it is not recommended to perform any training with the vaccinated animals or any other straining performances.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

The content of the vial has to be shaken prior to use.

4.6 Adverse effects

Adequate local reaction (usually sized as a pea) may develop in the administration site of the vaccine, and it disappears within 3 weeks. Hypersensitivity develops rarely.

4.7 Use during pregnancy and lactation

It is not appropriate for general reasons to vaccinate in the last two weeks prior to labour (handling, restlessness, antibody onset, etc.).

4.8 Interaction with other medicinal products and other forms of interaction

Biocan R vaccine may be used separately, simultaneously or in combination with other Biocan vaccines:

A/ Biocan R vaccine may be used as a diluent for other lyophilised Biocan vaccines (for example DHPPi, DP, P).

B/ Biocan R vaccine may be administered simultaneously or with liquid vaccines Biocan C, Biocan B, Biocan M and Biocan L.

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.

4.9 Posology and method of administration

Dosage - 1 ml regardless of age, weight and breed of the individual; but at the earliest in the 12th week of age.

Method of administration:

- subcutaneous, best in the region behind the shoulder blade.
- intramuscular, best to the muscle of the rear limb.

Animals are vaccinated from the age of 3 months. The onset of protective immunity is within 14 days after immunisation. Animals vaccinated earlier than at the age of 3 months must be revaccinated after reaching this age (minimal 14 day interval between vaccinations must be observed). Animals vaccinated for the first time, at the age of 3 – 12 months, must be revaccinated in 1 year after the first application of the vaccine. Revaccination performed one year after the first vaccine protects animals against rabies for at least 2 years. In order to maintain immunity, it is recommended to revaccinate in accordance with veterinary regulations of each country.

Recommended vaccination scheme for Biocan

Age of the puppy	Infectious situation		
	Favourable	Unfavourable Parvovirosis	Unfavourable Distemper
5 - 6 weeks		Puppy (P) + C	Puppy (DP) + C
7 -8 weeks		Puppy (P) + C	Puppy (DP) + C
8 -10 weeks	DHPPi + L	DHPPi + L	DHPPi + L
12 -16 weeks	DHPPi + LR	DHPPi + LR	DHPPi + LR
Yearly revaccination	DHPPi + LR	DHPPi + LR	DHPPi + LR

Note:

Vaccines in the brackets indicate a possibility of an alternative vaccination instead of Biocan Puppy vaccine.

Vaccines labelled +C, +L, +LR indicate a possibility of simultaneous or combined usage with other Biocan vaccines (e.g. DHPPi, DHP, DP, DH, P, Puppy).

Additional possible vaccinations: Biocan M – vaccine against Microsporum canis of dogs and cats for usage from the age of 12 weeks.

4.10 Overdose (symptoms, first aid, antidotes), if necessary

A double vaccination dose has no adverse effect on the target animals.

4.11 Withdrawal period

No withdrawal periods.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: 97 Veterinary immunopreparations
ATC code: QI07AA02 Veterinary vaccines

The antigen in the vaccine is recognised as extraneous after an administration to the body of the vaccinated individual and a variety of defence mechanisms of the organism are being activated (macrophages, opsonins, interleukins, B lymphocytes, etc.), the result of which is production of specific antibodies against antigen determinants contained in the vaccine. These mechanisms are designed to prevent further development of infection after contracting the disease.

Animals are vaccinated from the age of 3 months. The onset of protective immunity is within 14 days after immunisation. Animals vaccinated earlier than at the age of 3 months must be revaccinated after reaching this age (minimal 14 day interval between vaccinations must be observed). Animals vaccinated for the first time, at the age of 3 – 12 months, must be revaccinated in 1 year after the first application of the vaccine. Revaccination performed one year after the first vaccine protects animals against rabies for at least 2 years. In order to maintain immunity, it is recommended to revaccinate in accordance with veterinary regulations of each country.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nutrimentum MEM, Algedratum, Thiomersalum
Cell culture used for vaccine production: BHK-21 derived from hamster kidney.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product, except lyophilised vaccines Biocan and liquid vaccines Biocan C, Biocan B, Biocan M and Biocan L.

6.3 Shelf life

24 months.
To be used within 8 hours after the first opening.

6.4 Special precautions for storage

Store in a dry and dark place at a temperature 2 – 8°C.
Do not freeze!

6.5 Type and composition of internal packaging

Inner package is glass vial with 1 ml, 5 ml, 10 ml, 20 ml, 50 ml or 100 ml of the vaccine.

A) plastic box with a cover with 10 holes:
10 × 1 ml of Biocan R vaccine

B) plastic box with a cover with 20 holes:
20 × 1 ml of Biocan R vaccine

C) plastic box with a cover with 100 holes:
50 × 1 ml of Biocan R vaccine
100 × 1 ml of Biocan R vaccine

D) plastic box with a cover with 10 holes:
1 × 5 ml 5 × 10 ml
5 × 5 ml 10 × 10 ml
10 × 5 ml

E) carton box
1 × 10 ml 1 × 20 ml 1 × 50 ml 1 × 100 ml
5 × 20 ml
10 ×20 ml
Package insert is a part of every package.

6.6 Special precautions for disposal of unused veterinary medicinal product or waste material from such product

All unused veterinary medicinal product or waste from this product must be disposed of according to the local regulations in force.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION:

DATE OF AUTHORISATION PROLONGATION:

10. DATE OF REVISION OF THE TEXT

May 2014

BIOVETA, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
e-mail: comm@bioveta.cz

LABELLING

PARTICULARS TO APPEAR ON OUTER PACKAGE

plastic box with a lid with 10, 20 and 100 wells / 10 × 1 ml, 20 × 1 ml, 50 × 1 ml, 100 × 1 ml
plastic box with a lid with 10 wells / 1 × 5 ml, 5 × 5 ml, 10 × 5 ml, 5 × 10 ml, 10 × 10 ml
carton box / 1 × 10 ml, 1 × 20 ml, 5 × 20 ml, 10 ×20 ml, 1 × 50 ml, 1 × 100 ml

1. NAME OF VETERINARY MEDICINAL PRODUCT

Biocan R suspension for injection
Inactivated vaccine against rabies

2. STATEMENT OF THE ACTIVE INGREDIENTS AND OTHER SUBSTANCES

Composition - 1 mL:
Active ingredient: *Virus rabiei* inactivatum, strain SAD Vnukovo-32 min. 2 IU
Excipients: Nutrimentum MEM, Algedratum, Thiomersalum

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 × 1 ml (or another size)

5. TARGET ANIMAL SPECIES

Dogs, cats, fur animals, cattle, horses, sheep, goats, pigs.

6. INDICATIONS

For active immunisation of target animal species against rabies.

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous, intramuscular.
Read the package insert before use.

8. WITHDRAWAL PERIOD

No withdrawal periods.

9. SPECIAL PRECAUTIONS, IF NECESSARY

The content of the vial has to be shaken prior to use. Vaccinate only clinically healthy individuals in a proper nutritional condition. Possible anti-parasitic treatment should precede vaccination at least ten days. One week after the vaccination, it is not recommended to perform any training with the vaccinated animals or any other straining performances.

10. EXPIRY DATE

EXP:
To be used within 8 hours after the first opening.

11. SPECIAL STORAGE CONDITIONS

Store in a dry and dark place at a temperature 2 – 8°C.
Do not freeze!
Do not use the product after shelf life indicated on the cover.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE, IF NECESSARY

Disposal of packaging materials and unused product residues must be performed in accordance with regulations in force.

13. THE WORDS „FOR ANIMAL TREATMENT ONLY“ AND CONDITIONS OR LIMITATIONS CONCERNING RELEASE AND USAGE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription!

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

Keep out of the reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

17. MANUFACTURER'S BATCH NUMBER

Batch:

BIOVETA, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
e-mail: comm@bioveta.cz

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

glass vial / 50 ml, 100 ml

1. NAME OF VETERINARY MEDICINAL PRODUCT

Biocan R suspension for injection
Inactivated vaccine against rabies

2. STATEMENT OF THE ACTIVE INGREDIENTS AND OTHER SUBSTANCES

Composition - 1 mL:
Active ingredient: *Virus rabiei* inactivatum, strain SAD Vnukovo-32 min. 2 IU
Excipients: Nutrimentum MEM, Algedratum, Thiomersalum

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

1 × 50 ml/ 1× 100 ml

5. TARGET ANIMAL SPECIES

Dogs, cats, fur animals, cattle, horses, sheep, goats, pigs.

6. INDICATIONS

For active immunisation of target animal species against rabies.

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous, intramuscular.
Read the package insert before use.

8. WITHDRAWAL PERIOD

No withdrawal periods.

9. SPECIAL PRECAUTIONS, IF NECESSARY

The content of the vial has to be shaken prior to use. Vaccinate only clinically healthy individuals in a proper nutritional condition. Possible anti-parasitic treatment should precede vaccination at least ten days. One week after the vaccination, it is not recommended to perform any training with the vaccinated animals or any other straining performances.

10.EXPIRY DATE

EXP:
To be used within 8 hours after the first opening.

11.SPECIAL STORAGE CONDITIONS

Store in a dry and dark place at a temperature 2 – 8°C.
Do not freeze!
Do not use the product after shelf life indicated on the cover.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE, IF NECESSARY

Disposal of packaging materials and unused product residues must be performed in accordance with regulations in force.

13. THE WORDS „FOR ANIMAL TREATMENT ONLY“ AND CONDITIONS OR LIMITATIONS CONCERNING RELEASE AND USAGE, IF APPLICABLE

Only for animals!
Available only on veterinary prescription!

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

Keep out of the reach of children.

15.NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16.MARKETING AUTHORISATION NUMBER(S)

17.MANUFACTURER'S BATCH NUMBER

Batch:

BIOVETA, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
e-mail: comm@bioveta.cz

MINIMUM PARTICULAR TO APPEAR ON SMALL PACKAGE
glass vial / 5 ml, 10 ml, 20 ml

1. NAME OF VETERINARY MEDICINAL PRODUCT

Biocan R suspension for injection
Inactivated vaccine against rabies

2. QUANTITY OF ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Composition - 1 mL: *Virus rabiei* inactivatum, strain SAD Vnukovo-32 – min. 2 IU

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

5 doses/ 10 doses/ 20 doses

4. ROUTE OF ADMINISTRATION

Subcutaneous, intramuscular.

5. WITHDRAWAL PERIOD

No withdrawal periods.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only. To be supplied only on veterinary prescription.

BIOVETA, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
e-mail: comm@bioveta.cz

MINIMUM PARTICULAR TO APPEAR ON SMALL PACKAGE

glass vial / 1 ml

1. NAME OF VETERINARY MEDICINAL PRODUCT

Biocan R
Vaccine against Rabies

2. QUANTITY OF ACTIVE SUBSTANCE

1 ml: *Virus rabiei* inact., strain SAD Vnukovo-32 min. 2 IU

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

1 dose

4. ROUTE OF ADMINISTRATION

SC, IM use

5. WITHDRAWAL PERIOD

No withdrawal periods.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only!

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bioveta a.s, Ivanovice na Hané

BIOVETA, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
e-mail: comm@bioveta.cz

PACKAGE INSERT

Biocan R suspension for injection
Inactivated vaccine against rabies
Virus rabiei inactivatum (min. 2 IU)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF VETERINARY MEDICINAL PRODUCT

Biocan R suspension for injection
Inactivated vaccine against rabies

3. STATEMENT OF THE ACTIVE INGREDIENTS AND OTHER SUBSTANCES

Composition - 1 mL:
Active ingredient - *Virus rabiei* inactivatum, strain SAD Vnukovo-32 min. 2 IU
Excipients - Nutrimentum MEM, Algedratum, Thiomersalum

4. INDICATIONS

For active immunisation of target animal species against rabies.

5. CONTRAINDICATIONS

Systemic febrile disease. Non-vaccinated animals, injured or in contact with rabies-infected animals. Animals, which bit or injured a human, may be vaccinated only after the termination of an observation period.

6. ADVERSE EFFECTS

Adequate local reaction (usually sized as a pea) may develop in the administration site of the vaccine, and it disappears within 3 weeks. Hypersensitivity develops rarely.

7. TARGET ANIMAL SPECIES

Dogs, cats, fur animals, cattle, horses, sheep, goats, pigs.

8. POSOLOGY FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Dosage - 1 ml regardless of age, weight and breed of the individual; but at the earliest in the 12th week of age.

Method of administration:
- subcutaneous, best in the region behind scapula.
- intramuscular, best to the muscle of the rear limb.

Animals are vaccinated from the age of 3 months. The onset of protective immunity is within 14 days after immunisation. Animals vaccinated earlier than at the age of 3 months must be revaccinated after reaching this age (minimal 14 day interval between vaccinations must be observed). Animals vaccinated for the first time, at the age of 3 – 12 months, must be revaccinated in 1 year after the first

application of the vaccine. Revaccination performed one year after the first vaccine protects animals against rabies for at least 2 years. In order to maintain immunity, it is recommended to revaccinate in accordance with veterinary regulations of each country.

Interaction with other medicinal products and other forms of interaction
Biocan R vaccine may be used separately, simultaneously or in combination with other Biocan vaccines:
A) Biocan R vaccine may be used as a diluent for other lyophilised Biocan vaccines (for example DHPPi, DP, P).
B) Biocan R vaccine may be administered simultaneously or with liquid vaccines Biocan C, Biocan B, Biocan M and Biocan L.

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.

Recommended vaccination scheme for Biocan

Age of the puppy	Infectious situation		
	Favourable	Unfavourable Parvovirosis	Unfavourable Distemper
5 - 6 weeks		Puppy (P) + C	Puppy (DP) + C
7 -8 weeks		Puppy (P) + C	Puppy (DP) + C
8 -10 weeks	DHPPi + L	DHPPi + L	DHPPi + L
12 -16 weeks	DHPPi + LR	DHPPi + LR	DHPPi + LR
Yearly revaccination	DHPPi + LR	DHPPi + LR	DHPPi + LR

Note:
Vaccines in the brackets indicate a possibility of an alternative vaccination instead of Biocan Puppy vaccine.
Vaccines labelled +C, +L, +LR indicate a possibility of simultaneous or combined usage with other Biocan vaccines (e.g. DHPPi, DHP, DP, DH, P, Puppy).

Additional possible vaccinations: Biocan M – vaccine against Microsporum canis of dogs and cats for usage from the age of 12 weeks.

9. INSTRUCTIONS FOR PROPER ADMINISTRATION

The content of the vial has to be shaken prior to use.
Vaccinate only clinically healthy individuals in a proper nutritional condition. Possible anti-parasitic treatment should precede vaccination at least ten days. One week after the vaccination, it is not recommended to perform any training with the vaccinated animals or any other straining performances.

10. WITHDRAWAL PERIOD

No withdrawal periods.

BIOVETA, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
e-mail: comm@bioveta.cz

11. SPECIAL PRECAUTIONS FOR STORAGE

Store in a dry and dark place at a temperature 2 – 8°C.
Do not freeze!
To be used within 8 hours after the first opening.

12. SPECIAL WARNINGS

Not applicable.

13. Special PRECAUTIONS for the disposal of unused product or waste, if necessary

All unused veterinary medicinal product or waste from this product must be disposed of according to the local regulations.

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST APPROVED

May 2014.

15. OTHER INFORMATION

For animal treatment only.
This veterinary medical product is available only on prescription.

Nature and contents of containers:

A) plastic box with a cover with 10 holes:
10 × 1 ml of Biocan R vaccine

B) plastic box with a cover with 20 holes:
20 × 1 ml of Biocan R vaccine

C) plastic box with a cover with 100 holes:
50 × 1 ml of Biocan R vaccine
100 × 1 ml of Biocan R vaccine

D) plastic box with a cover with 10 holes:
1 × 5 ml 5 × 10 ml
5 × 5 ml 10 × 10 ml
10 × 5 ml

E) carton box
1 × 10 ml 1 × 20 ml 1 × 50 ml 1 × 100 ml
5 × 20 ml
10 ×20 ml