

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 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 Parvovirus	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.

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 medicinal product is available only on prescription.

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