SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan R suspension for injection
HU: Biocan R vakcina A.U.V.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per 1 ml:

Active Substance:

Inactivated rabies virus, strain SAD Vnukovo-32	minimum 2.0 IU/ml

Adjuvant:

Aluminium hydroxide	2.0 mg

Excipient:

Thiomersal	0.1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Solution of light pink colour that may contain a fine sediment.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats, cattle, pigs, sheep, goats, horses and ferrets.

4.2 Indications for use, specifying the target species

For the active immunization of dogs, cats, cattle, pigs, sheep, goats, horses and ferrets (from 12 weeks of age) against rabies, for the prevention of infection and mortality caused by rabies.
The onset of immunity is 14-21 days after vaccination.
Duration of immunity is 1 year as a minimum after primary vaccination and 2 years as a minimum after revaccination.
In compliance with the provisions of European Pharmacopoeia, the efficacy was proved by challenge tests in cats and dogs and by serological tests in other target groups of animals. One year after subcutaneous or intramuscular vaccination, 100% dogs and cats were resistant to infection. Two years after intramuscular and subcutaneous vaccination 100% and 96% dogs, respectively, and 92% cats were resistant to infection. The resistance to challenge in dogs and cats and the results of serological tests in the other target groups of animals comply with the efficacy requirements of European Pharmacopoeia on inactivated vaccines against rabies within one and two years after vaccination.

4.3 Contraindications

Vaccination may be performed in healthy animals only.
Animals having symptoms of rabies or animals suspicious of having rabies should not be vaccinated.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
None
Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-vaccination seek medical advice immediately and show the package leaflet or label.

4.6 Adverse reactions (frequency and seriousness)

Occasionally, a transient oedema may occur in all target species at the site of injection after subcutaneous administration only, with a maximum of 7 mm in diameter, rarely associated with a feeling of discomfort. The reaction usually subsides within 10 days.
In ferrets, oedema may have 10 mm in diameter as a maximum.
A transient local sensitivity (rarely accompanied with oedema) might be exhibited in all target species at the site of injection after intramuscular application. This usually subsides within 7 days.
As with any vaccine occasional hypersensitivity reactions may occur. In such an event, appropriate antihistaminic treatment should be given immediately.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.
The product was not almost tested on lactating animals. Based on the limited data of vaccination of lactating animals, the vaccination did not result in an increased frequency of adverse reactions.

4.8 Interaction with other medicinal products and other forms of interaction

There are no data available on the interaction of this vaccine with other vaccines. Therefore, another vaccine should be applied 14 days before or after this product.

4.9 Amounts to be administered and administration route

Posology and method of administration
Shake the content of the vial before use.
A single dose of 1 mL is sufficient irrespective of age, weight or species of animal. Apply subcutaneously or intramuscularly.

Primary vaccination:
Animals of all target species should be vaccinated from the 12th week of age.
Use one dose of the vaccine for primary vaccination.

Revaccination:
Revaccinate animals with one dose of the vaccine one year after the primary vaccination.
Subsequent vaccinations should be performed every 2 years after the first revaccination (applied one year after the primary vaccination).

For dogs, the vaccination schedule should comply with the valid legal regulations!

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No other adverse reactions except those described under 4.6 (Adverse reactions) were recorded following a two-fold overdose. In case of a subcutaneous overdose, the local reaction was stronger (oedema of 12 mm in diameter as a maximum) compared to the application of a standard dose.

4.11 Withdrawal periods

Dogs, cats, ferrets: not applicable
Cattle, pigs, sheep, goats, horses: zero days

5. IMMUNOLOGICAL PROPERTIES

The vaccine stimulates active immunity in the target species against rabies.
ATC vet. Code: QI07AA02

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal	0.1 mg
Aluminium-hydroxide	2.0 mg

(in the form of 2% aluminium-hydroxide gel)

6.2 Incompatibilities

In the absence of compatibility studies this vaccine should not be mixed with other vaccines.

6.3 Shelf life

Shelf life of unopened vial: 2 years
Shelf life after first opening: 10 hours.

6.4. Special precautions for storage

Store in refrigerator (+2 to +8°C). Do not freeze.

6.5 Nature and composition of immediate packaging

The vaccine is supplied in Type I glass vials complying with Ph Eur, sealed with a rubber stopper and aluminium cap.
The vaccine is supplied in quantities of 10 x 1 ml, 20 x 1 ml, 25 x 1 ml, 50 x 1 ml and 100 x 1 ml; 1 x 5 ml, 5 x 5 ml, 10 x 5 ml; 1 x 10 ml, 5 x 10 ml, 10 x 10 ml; 1 x 20 ml, 5 x 20 ml, 10 x 20 ml
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused vaccine or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT