ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RABADROP, oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition 1 dose (1.8 ml):

Active substance:

Rabies virus SAD Clone attenuated $1.8x10^{6.0}$ $TCID_{50}$* –. $1.8x10^{8.5}$ $TCID_{50}$*

* Tissue culture infectious dose – 50%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

The bait is brown-green to brown, die-shaped or round and has a solid consistency. Inside the bait is a plastic blister with multi language printing "Attention – vaccine against rabies". The content of the blister (the vaccination strain with the stabilizing medium) is orange to red-violet suspension.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

For active immunisation of wild red foxes and raccoon dogs to prevent infection by rabies virus.

Duration of immunity: at least 12 months

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not put the baits in inhabited areas, roads and in the vicinity of water (lakes, rivers, water reservoirs). Vaccine baits are not intended for vaccination of domestic animals. Gastrointestinal signs potentially due to the indigestible blister material are possible.

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

The vaccine contains live attenuated microorganisms, therefore appropriate measures should be taken to prevent contamination of the person handling the vaccine and the collaborators, for example by wearing suitable protective clothing or gloves when handling and distributing the vaccine.

In case of accidental contact of humans with the active substance of the vaccine, immediately remove it by thoroughly rinsing with water and soap, seek medical advice immediately and show the package leaflet or the label to the physician.

Proposed first aid measures immediately after direct human exposure to the vaccine fluid should follow the recommendations of the WHO as outlined in the "WHO Guide for Rabies Pre- and Post-Exposure Prophylaxis (PEP) in Humans".

4.6 Adverse reactions (frequency and seriousness)

No adverse reactions have been observed.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Oral use.

The baits are distributed either manually or from an airplane in the areas where vaccination campaign against rabies takes place. Usually die-shaped baits are used for aerial distribution. The baits are intended to be ingested by foxes or raccoon dogs. The intake of one bait is sufficient to secure the active immunisation against rabies.

Concrete vaccination procedure is governed by local conditions, in particular by the density of the target animal population, the health situation (i.e. the incidence of rabies in the target animal population) and the associated vaccination campaign requirements.

The vaccination area should be as large as possible (preferably larger than 5,000 km^2). The vaccination campaigns in rabies-free areas should be designed in such a way that the area covers a 50 km belt ahead of the rabies front. The distribution rate depends on the topography, on the population density of the target species and on the epizootiological situation. Therefore the recommendations / request of the duly designated competent authority are followed concerning distribution rate, vaccination area, distribution/baiting method and other local/areal conditions as specified by the competent authority. A higher distribution density is recommended in areas with a high population density of foxes/raccoon dogs. Aerial distribution of the baits by any suitable flight devices (such as airplane, helicopter, drones or similar) is recommended for open or sparsely populated areas, and manual distribution in areas with a high human population.
Aerial baiting is not recommended in the vicinity of water (lakes, rivers, water reservoirs) or in densely populated areas. To protect regions which are free of rabies, baiting may be carried out to create a vaccination belt or in the form of spot vaccinations. The vaccination should be preferably carried out biannually, for a number of consecutive years, for at least two years after the last confirmed case of rabies in the region, however vaccination should not be attempted when temperature are expected to reach 30° C or more. Especially the vaccine bait no. 3 has higher stability at elevated ambient temperature.

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

The administration of the vaccine virus at 10 times the recommended dose induced no undesirable effect.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological for Canidae, live viral vaccines.
ATC vet code: QI07BD.

Mechanism of action
The contact between the vaccination virus and the mucous membrane of the vaccinated animal occurs by ingurgitation of the bait with vaccine virus and the virus burst into the organism through the mucous membrane. The vaccine is used for the induction of protective immunity in foxes and raccoon dogs by the oral route characterised by the induction of rabies antibodies.
.
Genetic marker
The genetic marker unique for vaccination strain was determined. Marker 11K is base G in nucleotide position 11228 located in L gene for viral RNA polymerase. Marker 3K is base C in nucleotide position 3128 located in M gene (more precisely non-coding part between M and G gene).
RABADROP is a live modified vaccine against rabies intended for oral administration to red foxes (*Vulpes vulpes*) and raccoon dogs (*Nyctereutes procyonoides*).

The active substance is the highly immunogenic and apathogenic rabies virus selected and cloned in order to reduce residual pathogenicity elimination after intracerebral administration in adult mice from MSV used for the production of RABADROP vaccine and in which selection steps were performed to prevent reversion to parental strain.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine:
Stabilizing medium (collagen, sodium chloride, trometamol, potassium glutamate, edetic acid, water for injection)

Bait material
Bait material no. 1:
Beef tallow, hard paraffin, paraffin oil, fish meal, biomarker - tetracycline hydrochloride

Bait material no. 2:
Palm oil, fish meal, hard paraffin, bergafat, biomarker - tetracycline hydrochloride

Bait material no. 3:
Beef tallow, palm oil, fish meal, hard paraffin, bergafat, biomarker - tetracycline hydrochloride

The biomarker may not be part of the bait if required by specific tender conditions. Non-use of the biomarker has no negative impact on the acceptability of baits.

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years at -20°C and below
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.

Stability of preparation under laboratory conditions was shown for 7 days at 25°C, 5 days at 30 °C and 3 days at 35 °C.

6.4. Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

One dose of vaccine is filled into aluminium-PVC plastic blisters, covered with bait.

Package sizes:

a) For manual placement

Vaccine is packed in a cardboard box with the fixation grid with 20 pcs of baits.

Group packaging in a cardboard box is 30x20 pcs of baits

OR

Vaccine is packed in PE plastic bags with 30 pcs of baits.

b) For aerial distribution

Vaccine baits are packed in PE bags or PE sleeves which are placed in cardboard boxes for 700 pcs (1 x 700 pcs of baits in case of PE sleeve or 2 x 350 pcs of baits in case of PE bags).

Package leaflet is part of every packaging.
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 veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bioveta, a.s., Komenského 212/12
683 23 Ivanovice na Hané
Česká republika

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State´s competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.