

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
RABADROP, oral suspension**

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

Marketing authorisation holder and manufacturer responsible for batch release:

Bioveta, a.s., Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RABADROP, oral suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Composition 1 dose (1.8 ml):

Active substance:

Rabies virus SAD Clone attenuated $1.8 \times 10^{6.0}$ TCID₅₀* – $1.8 \times 10^{8.5}$ TCID₅₀*

* Tissue culture infectious dose – 50%

Excipient:

Stabilizing medium

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.

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. INDICATION(S)

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

Duration of immunity: at least 12 months

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

No adverse reactions have been observed.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 km²). 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 temperatures are expected to reach 30° C or more. Especially vaccine bait no. 3 has higher stability at elevated ambient temperature.

9. ADVICE ON CORRECT ADMINISTRATION

.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

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.

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”.

Pregnancy and lactation:

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

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

Tenfold dose of the vaccine has no side effects on the target species and other animal species (e.g. cat, rodent etc.).

Incompatibilities:

Compatibility studies are not available.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

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

Package sizes:

a) For manual placement

Vaccine is packed in 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 sleeves 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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.