ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec oral suspension for foxes and raccoon dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1.7 ml) contains:

Active substance:
Attenuated live rabies vaccine virus, strain SPBN GASGAS: $10^{6.8}$ FFU* - $10^{8.1}$ FFU*
(* Focus Forming Units)

Excipients:

Qualitative composition of excipients and other constituents
Vaccine:
Water for injections
Sucrose
Gelatin (porcine)
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Neomycin sulfate
Bait:
Fishmeal
Palm fat
Coconut fat
Paraffin
Oxytetracycline hydrochloride (may be added as biomarker if requested by authorities)

The suspension has a yellow colour in a frozen state and a reddish colour in the liquid state.
The baits are rectangular, brownish coloured and have an intensive smell.

3. CLINICAL INFORMATION

3.1 Target species

Foxes, raccoon dogs

3.2 Indications for use for each target species

For the active immunization of foxes and raccoon dogs against rabies to prevent infection and mortality.
Onset of immunity: not established
Duration of immunity: at least 12 months.

3.3 Contraindications

None.

3.4 Special warnings

Vaccine baits are not intended for vaccination of domestic animals.

Gastrointestinal signs (potentially due to the indigestible blister material) have been reported in dogs following accidental ingestion of the bait.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Handle the baits with care. It is recommended to wear disposable gloves when handling and distributing baits. In case of contact of the vaccine fluid, 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.

Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process,

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Target species: foxes, racoon dogs.

No adverse reactions have been observed.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

The intake of single bait is sufficient to ensure active immunisation to prevent infection by rabies virus. The baits are distributed by hand or by air within the framework of vaccination campaigns against rabies.

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) neither in densely populated areas. The vaccination should be preferably carried out biannually (e.g. in spring and autumn), for a number of consecutive years, for at least two years after the last confirmed case of rabies in the region; however, bait distribution should be avoided during seasons when temperatures and/or climatic conditions are expected to compromise bait and vaccine stability. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidots)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

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.
Restricted to duly designated competent administrative authorities.

Official control authority batch release is required for this product.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

Rabitec is a live modified rabies vaccine for oral administration to foxes and raccoon dogs.
Immunized animals are protected against field rabies virus infection and do not transmit rabies.
In contrast to its parental strain SAD B19, the Rabitec vaccine's active ingredient proved to be apathogenic for immunocompetent mice, the most sensitive species for rabies virus infection.

The active ingredient is a quadruple highly attenuated genetically modified rabies virus construct, derived from the SAD B19 vaccine strain. The genome carries mutations in the G-protein (glycoprotein) located at 2 independent loci of the genome (at amino acid positions 194 and 333 in G-protein), where all three nucleotides 'codon' were exchanged resulting in amino acid changes at both positions. In addition, the genome carries an exact duplicate of the modified immune-relevant G-protein (glycoprotein) gene, which results in the significant higher expression of the G protein gene. As each of these modifications on the genome were shown to further attenuate the SAD B19 virus

strain, their multiple effect helps to avoid the reversion to the parental strain. Finally, the pseudogen located between the G – and L-gene has been deleted.

A differentiation of this vaccine virus from any other rabies virus strains is possible, including its parental strain, for example by PCR methods.

Rabitec is used for the induction of the protective immunity in foxes and raccoon dogs by the oral route characterised by the induction of rabies virus specific (neutralising) antibodies induced primarily by the G-protein (glycoprotein).

No field studies were conducted.

The efficacy of the vaccine was demonstrated in laboratory studies.

4.1 ATCvet code:

ATCvet code: QI07BD
To stimulate immunity of foxes and raccoon dogs against rabies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years at/below -15 °C.
Stability after distribution in the environment was shown for 7 days at temperatures up to 25 °C.

5.3 Special precautions for storage

Store and transport frozen, below -15 °C.
Do not refreeze.
Baits should be distributed immediately after thawing. The thawed vaccine bait may be stored for 7 days between 2 °C– 8 °C before use; however baits for which the cooling chain was disrupted, because they were not stored in a refrigerator, should be destroyed.

5.4 Nature and composition of immediate packaging

The vaccine suspension is filled in polymer/aluminium blisters which are embedded in a bait matrix attractive for the target species. Baits are packed in plastic foil sleeves or bags in cardboard boxes of:

1 x 800 units
4 x 200 units
40 x 20 units

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/219/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 01/12/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 800 baits (1 x 800 units, 4 x 200 units or 40 x 20 units**)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec oral suspension for foxes and raccoon dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1,7 ml) contains:
Active substance:
Attenuated live rabies vaccine virus, strain SPBN GASGAS
$10^{6.8}$ FFU*/dose - $10^{8.1}$ FFU*/dose (* Focus Forming Units)

3. PACKAGE SIZE

1 x 800 units
4 x 200 units
40 x 20 units

4. TARGET SPECIES

Foxes, raccoon dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Distribution of baits manually or by air.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yy}
Baits should be distributed immediately after thawing.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport frozen.
Do not refreeze.

As an exception, the thawed vaccine may be stored for up to 7 days at 2 °C - 8 °C before use.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/219/001
EU/2/17/219/002
EU/2/17/219/003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PVC/Aluminium blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yy}

HAZARD WARNING

Rabies vaccine.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Baits

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabitec

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yy}

HAZARD WARNING

Rabies vaccine. Do not touch!

QR code – https:\\www.ceva.de\service\rabitec

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Rabitec oral suspension for foxes and raccoon dogs

2. Composition

Each dose (1.7 ml) embedded in bait contains:

Active substance:
Attenuated live rabies vaccine virus, strain SPBN GASGAS: $10^{6.8}$ FFU* - $10^{8.1}$ FFU*
(* Focus Forming Units)

The suspension has a yellow colour in a frozen state and a reddish colour in the liquid state.
The baits are rectangular, brown coloured and have an intensive smell.

3. Target species

Foxes, raccoon dogs

4. Indications for use

For the active immunization of foxes and raccoon dogs against rabies to prevent infection and mortality.
Onset of immunity: not established.
Duration of immunity: at least 12 months.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccine baits are not suitable for vaccination of domestic animals.

Gastrointestinal signs (potentially due to the indigestible blister material) have been reported in dogs following accidental ingestion of the bait.

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Handle the baits with care. It is recommended to wear disposable gloves when handling and distributing baits. In case of contact of the vaccine fluid, 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.

Since this vaccine has been prepared with live, attenuated microorganisms, appropriate measures should be taken to prevent contamination of the handler and other people that collaborate in the process.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Not known.

Overdose:
The administration of the vaccine at 10 times the recommended dose induced no undesirable effects.

7. Adverse events

Target species: foxes, racoon dogs.

Not known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.

The intake of single bait is sufficient to ensure active immunisation to prevent infection by rabies virus. The baits are distributed by hand or by air within the framework of vaccination campaigns against rabies.

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,) neither in densely populated areas. The vaccination should be preferably carried out biannually (e.g. in spring and autumn), for a number of consecutive years, for at least two years after the last confirmed case of rabies in the region, however, bait distribution should be avoided during seasons when temperatures and/or climatic conditions are expected to compromise bait and vaccine stability. 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.

9. Advice on correct administration

Baits should be distributed immediately after thawing.
Distribution of baits during periods with elevated temperatures is not recommended.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport frozen, below -15 °C.
Do not refreeze.
The thawed vaccine may be stored for up to 7 days at 2 °C - 8 °C before use; however baits for which the cooling chain was disrupted, because they were not stored in a refrigerator, should be destroyed.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and cardboard after Exp.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/17/219/001-003

Plastic foil sleeves or bags in cardboard boxes of:

1 x 800 units
4 x 200 units
40 x 20 units

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Ceva Santé Animale
10 av. de La Ballastière
33500 Libourne
France
Phone number: 00 800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

IDT Biologika GmbH
Am Pharmapark
06861 Dessau-Rosslau
Germany

Ceva Tiergesundheit (Riems) GmbH
An der Wiek 7
17493 Greifswald - Insel Riems
Germany

17. Other information

Liquid vaccine contained in a polymer/aluminium blisters which are embedded in a bait matrix attractive for the target species.