ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabigen SAG2 oral suspension, for red foxes and raccoon dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance :

Live attenuated rabies virus, SAG2 strain minimum 8 log10 CCID50*/dose

* CCID50 : Cell Culture Infective Dose 50%

Excipients :

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

4. CLINICAL PARTICULARS

4.1 Target species

Red foxes (*Vulpes vulpes*) and raccoon dogs (*Nyctereutes procyonoides*).

4.2 Indications for use, specifying the target species

For the active immunisation of red foxes and raccoon dogs to prevent infection by rabies virus.
The duration of protection is of at least 6 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

Special precautions for use in animals

Baits shall not be distributed in inhabited areas, roads and watery areas.

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

It is recommended to wear rubber gloves.
People handling and distributing this vaccine should be vaccinated against rabies.
Immunocompromised/immunosuppressed individuals must not be allowed to handle this vaccine.
In the event of human exposure to the active ingredient of the vaccine, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

No adverse events have been reported in the target species.
As this vaccine presentation contains traces of gentamicin and contains tetracycline as biomarker, occasional hypersensitivity reactions may be observed in domestic animals that have accidentally ingested the bait.

Vomiting due to gastric intolerance (potentially due to the aluminium/PVC sachet as part of the bait vaccine), in dogs which have accidentally ingested the bait, has been reported.

4.7 Use during pregnancy, lactation or lay

The safety of the vaccine in pregnant and lactating animals has not been investigated.
However rabies virus and attenuated rabies vaccine viruses do not usually accumulate in reproductive organs and are not known to directly affect reproductive functions.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The baits are distributed by land or by air within the framework of vaccination campaigns against rabies. They are intended to be eaten by foxes / raccoon dogs. The intake of a single bait is sufficient to ensure active immunisation to prevent infection by rabies virus.

The distribution rate depends on the topography and on the population of the target species.

The minimum distribution rate is:
- 13 baits per square km over the areas where fox /raccoon dog density indexes were equal or less than 3 foxes / raccoon dogs seen per 10 km.
- 20 baits per square km over the areas where fox / raccoon dog density indexes were more than 3 foxes / raccoon dogs seen per 10 km.

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

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

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccines
ATCvet code: QI07BD.

Rabigen SAG2 is a live modified rabies vaccine for oral administration to red foxes (*Vulpes vulpes*) and raccoon dogs (*Nyctereutes procyonoides*).

The active ingredient is a double low virulence mutant isolated from the SAD Bern strain of rabies virus by two successive selection steps in order to avoid natural reversion to the parental strain.

It is used for the active immunisation of foxes and raccoon dogs characterised by the induction of rabies specific antibodies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vaccine :
Disodium phosphate - Potassium dihydrogen phosphate - Glutamic acid – Saccharose – Gelatin – Tryptone - Lactalbumin hydrolysate - Sodium chloride - Water for injection

Appetent matrix (bait) :
Rhodor 7046R antifoam - Tetracycline (Hcl) HD - EVA (Ethyl Vinyl Acetate) - White soft paraffin - Paraffin 50/52° C - Seah Saur - Natural fish aroma

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years at -20°C and 2 days at +25°C.

6.4. Special precautions for storage

Store in a freezer at -40°C to -20°C.
Protect from light. Keep the boxes tightly closed.

6.5 Nature and composition of immediate packaging

Liquid vaccine contained within an aluminium/PVC sachet coated with an appetising matrix.
The baits are successively packed in boxes of:

- 200 units (4x50)
- 400 units (2x200)

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

Dispose of waste material and any unplaced baits at the end of the day of distribution by boiling or incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

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1ère Avenue 2065m L.I.D.
06516 Carros - France
tel: + 33 4 92 08 73 04
fax: + 33 4 92 08 73 48
e-mail: darprocedure@virbac.com

8. MARKETING AUTHORISATION NUMBERS

EU/2/00/021/001
EU/2/00/021/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/04/2000
Date of latest renewal: 16/03/2010

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of this veterinary medicinal product is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use the veterinary medicinal product must consult the relevant Member State's Competent Authority on the current vaccination policies prior to the import, sale, supply and/or use.

Restricted to duly designated competent administrative authorities.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

VIRBAC SA
L.I.D. 1ère Avenue - 2065 m
06516 Carros,
France

Manufacturing Authorisation issued on December 22nd 1997 by the Ministère de la solidarité, de la santé et de la protection sociale – Direction de la Pharmacie et du médicament – République Française.

Name and address of the manufacturer responsible for batch release

VIRBAC SA
L.I.D. 1ère Avenue - 2065 m
06516 Carros,
France

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

The import, sale, supply and/or use of this veterinary medicinal product is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use the veterinary medicinal product must consult the relevant Member State's Competent Authority on the current vaccination policies prior to the import, sale, supply and/or use.

Restricted to duly designated competent administrative authorities.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

200 UNIT BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabigen SAG2 oral suspension, for red foxes and raccoon dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Live attenuated rabies virus, SAG2 strain 8 log10 - CCID50*/dose

* CCID50: Cell Culture Infective Dose 50%

Excipients:
Palatable matrix (bait) containing a tetracycline biomarker

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

200 (4 x 50) vaccinal baits.

5. TARGET SPECIES

Red foxes *(Vulpes vulpes)* and raccoon dogs (*Nyctereutes procyonoides*).

6. INDICATION

For the active immunisation of red foxes and raccoon dogs to prevent infection by rabies virus.
The duration of protection is of at least 6 months.

7. METHOD AND ROUTE OF ADMINISTRATION

The baits are distributed by land or by air within the framework of vaccination_campaigns against rabies. They are intended to be eaten by foxes and raccoon dogs. The intake of a single bait is sufficient to ensure active immunisation to prevent infection by rabies virus.

The distribution rate depends on the topography and on the population of the target species.
This minimum distribution rate is:

- 13 baits per square km over the areas where fox / raccoon dog density indexes were equal or less than 3 foxes / raccoon dogs seen per 10 km.

- 20 baits per square km over the areas where fox / raccoon dog density indexes were more than 3 foxes / raccoon dogs seen per 10 km.

Read the package leaflet before use.

8. SPECIAL WARNINGS, IF NECESSARY

It is recommended to wear rubber gloves.

People handling and distributing this vaccine should be vaccinated against rabies.

Immunocompromised/immunosuppressed individuals must not be allowed to handle this vaccine.
In the event of human exposure to the active ingredient of the vaccine, seek medical advice immediately and show the package leaflet i or the label to the physician.

No adverse events have been reported in the target species.
As this vaccine presentation contains traces of gentamicin and contains tetracycline as biomarker, occasional hypersensitivity reactions may be observed in domestic animals that have accidentally ingested the bait.
Vomiting due to gastric intolerance (potentially due to the aluminium/PVC sachet as part of the bait vaccine), in dogs which have accidentally ingested the bait, has been reported.

9. EXPIRY DATE

EXP : {month/year}

10. SPECIAL STORAGE CONDITIONS

Store in a freezer at -40°C to -20°C.
Protect from light. Keep the boxes tightly closed.

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material and any unplaced baits at the end of the day of distribution by boiling or incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.
Restricted to duly designated competent administrative authorities.
The import, sale, supply and/or use of this veterinary medicinal product is or may be prohibited in certain Member States on the whole or part of their territory, see package insert for further information.

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

Keep out of the reach and sight of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère Avenue 2065m L.I.D.
06516 Carros - France

15. MARKETING AUTHORISATION NUMBER

EU/2/00/021/001

16. MANUFACTURER'S BATCH NUMBER

BN: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

400 UNIT BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabigen SAG2 oral suspension, for red foxes and raccoon dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Live attenuated rabies virus, SAG2 strain 8 log10 - CCID50*/dose

* CCID50: Cell Culture Infective Dose 50%

Excipients:
Palatable matrix (bait) containing a tetracycline biomarker

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

400 (2 x 200) vaccinal baits.

5. TARGET SPECIES

Red foxes *(Vulpes vulpes)* and raccoon dogs (*Nyctereutes procyonoides*).

6. INDICATION

For the active immunisation of red foxes and raccoon dogs to prevent infection by rabies virus.
The duration of protection is of at least 6 months.

7. METHOD AND ROUTE OF ADMINISTRATION

The baits are distributed by land or by air within the framework of vaccination_campaigns against rabies. They are intended to be eaten by foxes / raccoon dogs. The intake of a single bait is sufficient to ensure active immunisation to prevent infection by rabies virus.

The distribution rate depends on the topography and on the population of the target species.
This minimum distribution rate is:

- 13 baits per square km over the areas where fox / raccoon dog density indexes were equal or less than 3 foxes / raccoon dogs seen per 10 km.

- 20 baits per square km over the areas where fox / raccoon dog density indexes were more than 3 foxes / raccoon dogs seen per 10 km.

Read the package leaflet before use.

8. SPECIAL WARNINGS, IF NECESSARY

It is recommended to wear rubber gloves.

People handling and distributing this vaccine should be vaccinated against rabies.

Immunocompromised/immunosuppressed individuals must not be allowed to handle this vaccine.
In the event of human exposure to the active ingredient of the vaccine, seek medical advice immediately and show the package leaflet or the label to the physician.

No adverse events have been reported in the target species.
As this vaccine presentation contains traces of gentamicin and contains tetracycline as biomarker, occasional hypersensitivity reactions may be observed in domestic animals that have accidentally ingested the bait.
Vomiting due to gastric intolerance (potentially due to the aluminium/PVC sachet as part of the bait vaccine), in dogs which have accidentally ingested the bait, has been reported.

9. EXPIRY DATE

EXP: {month/year}

10. SPECIAL STORAGE CONDITIONS

Store in a freezer at -40°C to -20°C.
Protect from light. Keep the boxes tightly closed.

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material and any unplaced baits at the end of the day of distribution by boiling or incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.
Restricted to duly designated competent administrative authorities.
The import, sale, supply and/or use of this veterinary medicinal product is or may be prohibited in certain Member States on the whole or part of their territory, see package insert for further information.

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

Keep out of the reach and sight of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère Avenue 2065m L.I.D.
06516 Carros - France

15. MARKETING AUTHORISATION NUMBER

EU/2/00/021/002

16. MANUFACTURER'S BATCH NUMBER

BN: {number}

MINIMUM PARTICULARS TO APPEAR ON SACHETS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabigen SAG2 oral suspension, for red foxes and raccoon dogs.

2. BATCH NUMBER

BN: {number}

3. EXPIRY DATE

EXP: {month/year}

4. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

RABIES VACCINE DO NOT TOUCH

Informative phone number: + 33 4 92 08 73 04

PARTICULARS TO APPEAR ON BAITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabigen SAG2 oral suspension, for red foxes and raccoon dogs.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère Avenue 2065 M L.I.D
06516 Carros
France

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

BN: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

RABIES VACCINE DO NOT TOUCH

Informative phone number: + 33 4 92 08 73 04

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Rabigen SAG2 oral suspension, for red foxes and raccoon dogs.

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

VIRBAC S.A.
1ère Avenue 2065m L.I.D.
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabigen SAG2 oral suspension, for red foxes and raccoon dogs.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance:
Live attenuated rabies virus, SAG2 strain 8 log10 CCID50*/dose

* CCID50: Cell Culture Infective Dose 50%

Excipients:
Palatable matrix (bait) containing a tetracycline biomarker

4. INDICATION

For the active immunisation of red foxes and raccoon dogs to prevent infection by rabies virus.
The duration of protection is of at least 6 months.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

No adverse events have been reported in the target species.
As this vaccine presentation contains traces of gentamicin and contains tetracycline as biomarker, occasional hypersensitivity reactions may be observed in domestic animals that have accidentally ingested the bait.
Vomiting due to gastric intolerance (potentially due to the aluminium/PVC sachet as part of the bait vaccine), in dogs which have accidentally ingested the bait, has been reported.

7. TARGET SPECIES

Red foxes *(Vulpes vulpes)* and raccoon dogs (*Nyctereutes procyonoides*).

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

The intake of a single bait is sufficient to ensure active immunisation to prevent infection by rabies virus.

The baits are distributed by land or by air within the framework of vaccination campaigns against rabies. They are intended to be eaten by foxes / raccoon dogs.

The distribution rate depends on the topography and on the population of the target species.

This minimum distribution rate is:
- 13 baits per square km over the areas where fox / raccoon dog density indexes were equal or less than 3 foxes / raccoon dogs seen per 10 km.
- 20 baits per square km over the areas where fox / raccoon dog density indexes were more than 3 foxes / raccoon dogs seen per 10 km.

9. ADVICE ON CORRECT ADMINISTRATION

Baits shall not be distributed in inhabited areas, roads and watery areas.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children
Store in a freezer at -40°C to -20°C.
Protect from light. Keep the boxes tightly closed.

12. SPECIAL WARNINGS

For animal treatment only.

It is recommended to wear rubber gloves.

People handling and distributing this vaccine should be vaccinated against rabies.

The safety of the vaccine in pregnant and lactating animals has not been investigated. However rabies virus and attenuated rabies vaccine viruses do not usually accumulate in reproductive organs and are not known to directly affect reproductive functions.

Immunocompromised/immunosuppressed individuals must not be allowed to handle this vaccine.
In the event of human exposure to the active ingredient of the vaccine, seek medical advice immediately and show the package leaflet or the label to the physician.

The import, sale, supply and/or use of this veterinary medicinal product is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use the veterinary medicinal product must consult the relevant Member State's Competent Authority on the current vaccination policies prior to the import, sale, supply and/or use.

Restricted to duly designated competent administrative authorities.

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

Dispose of waste material and any unplaced baits at the end of the day of distribution by boiling or incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu/

15. OTHER INFORMATION

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.

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