ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagen Omega 5 MU lyophilisate and solvent for suspension for injection for dogs and cats
Virbagen Omega 10 MU lyophilisate and solvent for suspension for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:

Lyophilisate:

5 MU presentation:
Recombinant Omega interferon of feline origin 5 MU*

10 MU presentation:
Recombinant Omega interferon of feline origin 10 MU*

*MU: Million Units

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sodium hydroxide 0.2 M
Sodium chloride
D-Sorbitol
Purified gelatin of porcine origin
Solvent:
Sodium chloride
Water for injections

Lyophilisate: white colour.
Solvent: colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Dogs:
Reduction of mortality and clinical signs of parvovirosis (enteric form) in dogs from one month of age.

Cats:

Treatment of cats infected with FeLV (Feline Leukemia Virus) and/or FIV (Feline Immunodeficiency Virus), in non-terminal clinical stages, from the age of 9 weeks. In a field study conducted, it was observed that there was:

- a reduction of clinical signs during the symptomatic phase (4 months)
- a reduction of mortality:
  - in anaemic cats, mortality rate of about 60 % at 4, 6, 9 and 12 months was reduced by approximately 30 % following treatment with interferon.
  - in non-anaemic cats, mortality rate of 50 % in cats infected by FeLV was reduced by 20 % following treatment with interferon. In cats infected by FIV, mortality was low (5 %) and was not influenced by the treatment.

3.3 Contraindications

Dogs: Vaccination during and after Virbagen Omega treatment is contraindicated, until the dog appears to have recovered.

Cats: as vaccination is contraindicated in the symptomatic phase of FeLV/FIV infections, the effect of Virbagen Omega on cat vaccination has not been evaluated.

3.4 Special warnings

No information on the induction of long-term adverse reactions is available in dog and cat, especially for autoimmune disorders. Such side effects have been described after multiple and long-term administration of type I interferon in man. The possibility of occurrence of autoimmune disorders in treated animals cannot therefore be ruled out and has to be balanced with the risk associated with FeLV/FIV infections.

Efficacy of the product on cats with a tumorous form of the infection by FeLV, or cats infected by FeLV or coinfected by FIV in terminal stages was not tested.
In the case of intravenous administration in cats, increased adverse reactions may be seen, e.g. hyperthermia, soft faeces, anorexia, decreased drinking or collapse.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Dogs and cats: it was shown that strict compliance with the recommended posology is compulsory to achieve clinical benefit.

Cats: In case of repeated treatments of chronic diseases associated with hepatic, cardiac and renal failure, the corresponding disease has to be monitored prior to administration of Virbagen Omega.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Decreased white blood cells[1], Decreased platelet count[1], Decreased red blood cell count[1], Elevated alanine aminotransferase (ALT)[1]
Common (1 to 10 animals / 100 animals treated):	Hyperthermia[2,3] Lethargy[2]

[1]Slight, Return to normal in the week following the last injection.
[2]Slight and Transient.
[3]3-6 hours after injection.

Cats:

Very common (>1 animal / 10 animals treated):	Decreased white blood cells[1], Decreased platelet count[1], Decreased red blood cell count[1], Elevated alanine aminotransferase (ALT)[1]
Common (1 to 10 animals / 100 animals treated):	Hyperthermia[2,3] Lethargy[2] Digestive tract disorders (e.g. Diarrhoea, Vomiting)[2]

[1]Slight, Return to normal in the week following the last injection.
[2]Slight and Transient.
[3]3-6 hours after injection.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

The use of supplementary supportive treatments improves prognosis. No interaction has been observed during the treatment with Virbagen Omega together with antibiotics, solution for rehydration, vitamins and non steroidal anti-inflammatory agents. However, as specific information on possible interactions of interferon with other products are missing, supplementary supportive treatments should be used cautiously and after a thorough risk/benefit analysis.

No information is available on the safety and efficacy of this product when used with any other vaccine. For dogs, it is recommended that no vaccines should be administered until the animal appears to have recovered. Cat vaccination during and after Virbagen Omega treatment is contraindicated as both FeLV and FIV infections are known to be immunosuppressive.

3.9 Administration routes and dosage

Dogs: Intravenous use
Cats: Subcutaneous use

The freeze-dried fraction must be reconstituted with 1 ml of the specific diluent to obtain, depending on the presentation, a limpid and colourless suspension containing 5 MU or 10 MU of recombinant interferon.

Dogs:

The reconstituted product should be injected intravenously once daily for 3 consecutive days.
The dose is 2.5 MU/kg bodyweight.

Cats:
The reconstituted veterinary medicinal product should be injected subcutaneously once daily for 5 consecutive days. The dose is 1 MU/kg bodyweight. Three separate 5-day treatments must be performed at day 0, day 14 and day 60.

The veterinary medicinal product should be used with the accompanying solvent only.

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

After a tenfold overdose in both dog and cat the following clinical signs have been observed:

- mild lethargy and drowsiness.
- slight increase of body temperature.
- slight increase of respiratory rate.
- slight sinus tachycardia.

These clinical signs disappear within 7 days without any particular treatment.

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

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QL03AB

Omega interferon of feline origin, produced by genetic engineering, is a type I interferon closely related to alpha interferon.

The exact mechanism of action of interferon omega is not perfectly known, but may involve enhancement of the non-specific defence of the body, in particular in the dog against canine parvovirosis and in the cat against feline retrovirosis (FeLV, FIV). Interferon does not act directly and specifically on the pathogenic virus, but exerts its effect by inhibition of the internal synthesis mechanisms of the infected cells.

After injection it is quickly bound to specific receptors of a large variety of cells. It is mainly in cells infected by virus that the mechanism of replication is stopped both by destruction of mRNA and by inactivation of translation proteins (2'5' oligo-adenylate synthetase activation).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8°C).
Do not freeze.
Store in the original package.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Type I glass vial closed with stopper made with butyl rubber polymer coated with a fluorocarbon polymer resin.

Solvent:
Type I glass vial of 1 ml of solvent closed with butyl elastomer rubber stopper.

For the 5 MU presentation:
Cardboard box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

For the 10 MU presentation:
Cardboard box containing 1 vial of lyophilisate and 1 vial with 1 ml of solvent
Cardboard box containing 2 vials of lyophilisate and 2 vials with 1 ml of solvent
Cardboard box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/01/030/001
EU/2/01/030/002
EU/2/01/030/003
EU/2/01/030/004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/11/2001

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 (*https://medicines.health.europa.eu/veterinary*).

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

Box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagen Omega 5 MU lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Lyophilisate:
Recombinant Omega interferon of feline origin 5 MU*

*MU : Million Units

3. PACKAGE SIZE

Box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent.

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: Intravenous use
Cats: Subcutaneous use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8°C).
Do not freeze.
Store in the original package.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/01/030/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagen Omega 10 MU lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Lyophilisate:
Recombinant Omega interferon of feline origin 10 MU*

*MU : Million Units

3. PACKAGE SIZE

Box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent.

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: Intravenous use
Cats: Subcutaneous use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2°C – 8°C).
Do not freeze.
Store in the original package.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/01/030/002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 2 vials of lyophilisate and 2 vials with 1 ml of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagen Omega 10 MU lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Lyophilisate:
Recombinant Omega interferon of feline origin 10 MU*

*MU : Million Units

3. PACKAGE SIZE

Box containing 2 vials of lyophilisate and 2 vials with 1 ml of solvent.

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: Intravenous use
Cats: Subcutaneous use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2°C – 8°C).
Do not freeze.
Store in the original package.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/01/030/003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1 vial of lyophilisate and 1 vial with 1 ml of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagen Omega 10 MU lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Lyophilisate:
Recombinant Omega interferon of feline origin 10 MU*

*MU : Million Units

3. PACKAGE SIZE

Box containing 1 vial of lyophilisate and 1 vial with 1 ml of solvent.

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: Intravenous use
Cats: Subcutaneous use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2°C – 8°C).
Do not freeze.
Store in the original package.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/01/030/004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LYOPHILISATE VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagen Omega

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 MU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LYOPHILISATE VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagen Omega

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 MU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SOLVENT VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbagen Omega solvent

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Virbagen Omega 5 MU lyophilisate and solvent for suspension for injection for dogs and cats
Virbagen Omega 10 MU lyophilisate and solvent for suspension for injection for dogs and cats

2. Composition

Each dose of 1 ml contains:

Active substance:

Lyophilisate:

5 MU presentation:
Recombinant Omega interferon of feline origin 5 MU*

10 MU presentation:
Recombinant Omega interferon of feline origin 10 MU*

*MU : Million Units

Lyophilisate: white colour
Solvent: colourless liquid

3. Target species

Dogs and cats.

4. Indications for use

Dogs:
Reduction of mortality and clinical signs of parvovirosis (enteric form) in dogs from one month of age.

Cats:
Treatment of cats infected with FeLV and/or FIV, in non-terminal clinical stages, from the age of 9 weeks. In a field study conducted, it was observed that there was:
- a reduction of clinical signs during the symptomatic phase (4 months)
- a reduction of mortality :
    - in anaemic cats, mortality rate of about 60 % at 4, 6, 9 and 12 months was reduced by approximately 30 % following treatment with interferon.
    - in non-anaemic cats, mortality rate of 50 % in cats infected by FeLV was reduced by 20 % following treatment with interferon. In cats infected by FIV, mortality was low (5 %) and was not influenced by the treatment.

5. Contraindications

Dogs: Vaccination during and after Virbagen Omega treatment is contra-indicated, until the dog appears to have recovered.

Cats: as vaccination is contra-indicated in the symptomatic phase of FeLV/FIV infections, the effect of Virbagen Omega on cat vaccination has not been evaluated.

6. Special warnings

Special warnings:

No information on the induction of long-term side effects is available in dog and cat, especially for autoimmune disorders. Such side effects have been described after multiple and long-term administration of type I interferon in man. The possibility of occurrence of autoimmune disorders in treated animals cannot therefore be ruled out and has to be balanced with the risk associated with FeLV/FIV infections.
Efficacy of the product on cats with a tumorous form of the infection by FeLV, or cats infected by FeLV or coinfected by FIV in terminal stages was not tested.
In the case of intravenous administration in cats, increased adverse reactions may be seen, e.g. hyperthermia, soft faeces, anorexia, decreased drinking or collapse.

Special precautions for safe use in the target species:

Dogs and cats: it was shown that strict compliance with the recommended posology is compulsory to achieve clinical benefit.

Cats: In case of repeated treatments of chronic diseases associated with hepatic, cardiac and renal failure, the corresponding disease has to be monitored prior to administration of Virbagen Omega.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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:

The use of supplementary supportive treatments improves prognosis. No interaction has been observed during the treatment with Virbagen Omega together with antibiotics, solution for rehydration, vitamins and non steroidal anti-inflammatory agents. However, as specific information on possible interactions of interferon with other products are missing, supplementary supportive treatments should be used cautiously and after a thorough risk/benefit analysis.

No information is available on the safety and efficacy when used with any other vaccine. For dogs, it is recommended that no vaccines should be administered until the animal appears to have recovered. Cat vaccination during and after Virbagen Omega treatment is contra-indicated as both FeLV and FIV infections are known to be immunosuppressive.

Overdose:

After a tenfold overdose in both dog and cat the following clinical signs have been observed:

- mild lethargy and drowsiness
- slight increase of body temperature.
- slight increase of respiratory rate

- slight sinus tachycardia.

These clinical signs disappear within 7 days without any particular treatment.

Major incompatibilities:

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the product.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):
Decreased white blood cells[1], Decreased platelet count[1], Decreased red blood cell count[1], Elevated alanine aminotransferase (ALT)[1]
Common (1 to 10 animals / 100 animals treated):
Hyperthermia[2,3] Lethargy[2]

[1]Slight, Return to normal in the week following the last injection.
[2]Slight and Transient.
[3]3-6 hours after injection.

Cats:

Very common (>1 animal / 10 animals treated):
Decreased white blood cells[1], Decreased platelet count[1], Decreased red blood cell count[1], Elevated alanine aminotransferase (ALT)[1]
Common (1 to 10 animals / 100 animals treated):
Hyperthermia[2,3] Lethargy[2] Digestive tract disorders (e.g. Diarrhoea, Vomiting)[2]

[1]Slight, Return to normal in the week following the last injection.
[2]Slight and Transient.
[3]3-6 hours after injection.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Dogs: The dose is 2.5 MU/kg bodyweight.
Cats: The dose is 1 MU/kg bodyweight.

The freeze-dried fraction must be reconstituted with 1 ml of the specific diluent to obtain, depending on the presentation, a limpid and colourless suspension containing 5 MU or 10 MU of recombinant interferon.
Dogs: The reconstituted product should be injected intravenously once daily for 3 consecutive days.
Cats: The reconstituted product should be injected subcutaneously once daily for 5 consecutive days.

Three separate 5-day treatments must be performed at day 0, day 14 and day 60.

The product should be used immediately after reconstitution.

9. Advice on correct administration

The freeze-dried fraction must be reconstituted with 1 ml of the specific diluent to obtain, depending on the presentation, a limpid and colourless suspension.

Dogs and cats: it was shown that strict compliance with the recommended posology is compulsory to achieve clinical benefit.

Cats: In case of repeated treatments of chronic diseases associated with hepatic, cardiac and renal failure, the corresponding disease has to be monitored prior to administration of Virbagen Omega
The use of supplementary supportive treatments improves prognosis.
The veterinary medicinal product should be used with the accompanying solvent only.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Store in the original carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

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/2/01/030/001
EU/2/01/030/002
EU/2/01/030/003
EU/2/01/030/004

For the 5 MU presentation:
Cardboard box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

For the 10 MU presentation:
Cardboard box containing 1 vial of lyophilisate and 1 vial with 1 ml of solvent
Cardboard box containing 2 vials of lyophilisate and 2 vials with 1 ml of solvent
Cardboard box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC
1ère Avenue 2065m LID
06516 CARROS
France

Local representatives and contact details to report suspected adverse reactions:

Österreich
VIRBAC Österreich GmbH
Hildebrandgasse 27
A-1180 Wien
Tel: + 43-(0) 1 21 834 260

België/Belgique/Belgien
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