ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA 5 MU for dogs and cats
VIRBAGEN OMEGA 10 MU 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

Solvent:
Isotonic sodium chloride solution 1 ml

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Lyophilisate: white pellet.
Solvent: colourless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.
Cats.

4.2 Indications for use, specifying the 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 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.

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

In some cases, during treatment, the following transitory clinical signs may be observed in dogs and cats:
A slight decrease in white blood cells, platelets and red blood cells, and rise in the concentration of alanine aminotransferase were observed very commonly in safety studies. These parameters return to normal in the week following the last injection.
Slight and transient clinical signs such as hyperthermia (3-6 hours after injection) lethargy and digestive signs (vomiting and soft faeces to mild diarrhoea, in cats only.) were commonly observed in safety studies.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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

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 from the concurrent use of this product with any 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.

4.9 Amounts to be administered and administration route

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 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 product should be used with the accompanying solvent only.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Interferons
ATCvet code : QL03AB

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sodium hydroxide 0.2 M
Sodium chloride
D-Sorbitol
Purified gelatin of porcine origin

Solvent:
Sodium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

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

6.4. Special precautions for storage

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

6.5 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 5MU presentation:
Cardboard box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

For the 10MU 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.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère Avenue - 2065m – L.I.D.
06516 CARROS
France

8. MARKETING AUTHORISATION NUMBERS

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first autorisation: 06.11.2001 / Date of last renewal: 21.11.2006

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://emea.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of VIRBAGEN OMEGA 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 VIRBAGEN OMEGA must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

ANNEX II

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

Name and address of the manufacturer of the biological active substance

Toray industries, Inc.
EhimePlant
1515 Tsutsui, Masaki-Cho, Iyogun
791-3193
Japan

Name and address of the manufacturer responsible for batch release

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

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

To be supplied only on veterinary prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA 5 MU for dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substance:

Lyophilisate:
Recombinant Omega interferon of feline origin 5 MU*

*MU : Million Units

Solvent:
Isotonic sodium chloride solution 1 ml

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The freeze-dried fraction must be reconstituted with 1 ml of the specific diluent to obtain a suspension containing 5 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 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 product should be used with the accompanying solvent only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

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 symptomatic phase of FeLV/FIV infections, effect of VIRBAGEN OMEGA on cat vaccination has not been evaluated.

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.

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.

10. EXPIRY DATE

EXP {month/year}
The product should be used immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Store in the original carton.
Once reconstituted use immediately.

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

Dispose of waste material in accordance with local requirements

13. 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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère Avenue - 2065 m – L.I.D.
06516 CARROS
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/01/030/001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA 10 MU for dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substance:

Lyophilisate:
Recombinant Omega interferon of feline origin 10 MU*

*MU : Million Units

Solvent:
Isotonic sodium chloride solution 1 ml

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The freeze-dried fraction must be reconstituted with 1 ml of the specific diluent to obtain a solution containing 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 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 product should be used with the accompanying solvent only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

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 symptomatic phase of FeLV/FIV infections, effect of VIRBAGEN OMEGA on cat vaccination has not been evaluated.

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.

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.

10. EXPIRY DATE

EXP {month/year}
The product should be used immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Store in the original carton.
Once reconstituted use immediately.

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

Dispose of waste material in accordance with local requirements.

13. 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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère Avenue - 2065 m - L.I.D.
06516 CARROS
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/01/030/002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA 10 MU for dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substance:

Lyophilisate:
Recombinant Omega interferon of feline origin 10 MU*

*MU : Million Units

Solvent:
Isotonic sodium chloride solution 1 ml

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The freeze-dried fraction must be reconstituted with 1 ml of the specific diluent to obtain a solution containing 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 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 product should be used with the accompanying solvent only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

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 symptomatic phase of FeLV/FIV infections, effect of VIRBAGEN OMEGA on cat vaccination has not been evaluated.

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.

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.

10. EXPIRY DATE

EXP {month/year}
The product should be used immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Store in the original carton.
Once reconstituted use immediately.

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

Dispose of waste material in accordance with local requirements.

13. 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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère Avenue - 2065 m – L.I.D.
06516 CARROS
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/01/030/003

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA 10 MU for dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substance:

Lyophilisate:
Recombinant Omega interferon of feline origin 10 MU*

*MU : Million Units

Solvent:
Isotonic sodium chloride solution 1 ml

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The freeze-dried fraction must be reconstituted with 1 ml of the specific diluent to obtain a solution containing 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 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 product should be used with the accompanying solvent only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

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 symptomatic phase of FeLV/FIV infections, effect of VIRBAGEN OMEGA on cat vaccination has not been evaluated.

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.

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.

10. EXPIRY DATE

EXP {month/year}
The product should be used immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Store in the original carton.
Once reconstituted use immediately.

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

Dispose of waste material in accordance with local requirements.

13. 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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère Avenue - 2065 m – L.I.D.
06516 CARROS
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/01/030/004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA 5 MU for dogs and cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Recombinant Omega interferon of feline origin 5 MU*/ ml

* MU: Million Units

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 MU

4. ROUTE(S) OF ADMINISTRATION

Dogs: Intravenous route
Cats: Subcutaneous route

5. WITHDRAWAL PERIOD(S)

Not applicable.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP: {month/year}
Once reconstituted use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA 10 MU for dogs and cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Recombinant Omega interferon of feline origin 10 MU*/ ml

* MU: Million Units

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 MU

4. ROUTE(S) OF ADMINISTRATION

Dogs: Intravenous route
Cats: Subcutaneous route

5. WITHDRAWAL PERIOD(S)

Not applicable.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP: {month/year}
Once reconstituted use immediately

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA
Solvent for suspension for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Isotonic sodium chloride solution

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

Dogs: Intravenous route
Cats: Subcutaneous route

5. WITHDRAWAL PERIOD(S)

Not applicable.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
VIRBAGEN OMEGA 5 MU for dogs and cats
VIRBAGEN OMEGA 10 MU for dogs and cats

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

VIRBAC
1ère Avenue - 2065 m - L.I.D.
06516 CARROS
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

VIRBAGEN OMEGA 5 MU for dogs and cats
VIRBAGEN OMEGA 10 MU for dogs and cats

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

Each dose of 1ml 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

Solvent:
Isotonic sodium chloride solution 1 ml

Lyophilisate: white pellet
Solvent: colourless liquid

4. INDICATION(S)

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. ADVERSE REACTIONS

In some cases, during treatment, the following transitory clinical signs may be observed in dogs and cats:
A slight decrease in white blood cells, platelets and red blood cells, and rise in the concentration of alanine aminotransferase were observed very commonly in safety studies. These parameters return to normal in the week following the last injection.
Slight and transient clinical signs such as hyperthermia (3-6 hours after injection) lethargy and digestive signs (vomiting and soft faeces to mild diarrhoea, in cats only) were commonly observed in safety studies.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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

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 product should be used with the accompanying solvent only.

10. WITHDRAWAL PERIOD(S)

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 after the expiry date stated on the label.

Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species

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 use in animals

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 insert 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 from the concurrent use of this product with any 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 (symptoms, emergency procedures, 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.

Incompatibilities

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

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

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

For the 10MU 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.

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

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