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

Vial containing lyophilisate:

Active substance:

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

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

*MU : Million Units

Vial containing solvent:

Isotonic sodium chloride solution 1 ml

Excipients:

For a full list of excipients, see section 6.1.

3.  PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

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 insert 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:

- hyperthermia (3-6 hours after injection)
- vomiting
- soft faeces to mild diarrhoea, in cats only.

In addition, a slight decrease in white blood cells, platelets and red blood cells, and rise in the concentration of alanine aminotransferase may be observed. These parameters return to normal in the week following the last injection.

- transient fatigue during the treatment, in cats only.

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 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: QL03 AB

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

Sodium hydroxide 0.2 M, sodium chloride, D-Sorbitol, purified gelatin of porcine origin.

6.2 Incompatibilities

Do not mix with any other vaccine/immunological product, except the solvent supplied for use with the product.

6.3 Shelf life

2 years.
The product should be used immediately after reconstitution.

6.4 Special precautions for storage

Store and transport at 4°C ± 2°C.
Do not freeze.
Store in the original carton.

6.5 Nature and composition of immediate packaging

For the 5MU presentation:
Box containing 5 vials (glass with stoppers made with butyl rubber polymer coated with a fluorocarbon polymer resin ) of powder fraction and 5 vials (glass with butyl elastomer rubber stopper) with 1 ml of solvent.

For the 10MU presentation:
Box containing 1 vial (glass with stoppers made with butyl rubber polymer coated with a fluorocarbon polymer resin ) of powder fraction and 1 vial (glass with butyl elastomer rubber stopper) with 1 ml of solvent.
Box containing 2 vials (glass with stoppers made with butyl rubber polymer coated with a fluorocarbon polymer resin ) of powder fraction and 2 vials (glass with butyl elastomer rubber stopper) with 1 ml of solvent.
Box containing 5 vials (glass with stoppers made with butyl rubber polymer coated with a fluorocarbon polymer resin ) of powder fraction and 5 vials (glass with butyl elastomer rubber stopper) with 1 ml of solvent.

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 SA
L.I.D. 1ère Avenue - 2065 m
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

06.11.2001 / 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 (EMA) [http://www.ema.europa.eu](http://www.ema.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 AUTHORITY REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORITY 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 SA
L.I.D. 1ère Avenue - 2065 m
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 AND OTHER SUBSTANCES**

**Vial containing lyophilisate:**

**Active substance**

Recombinant Omega interferon of feline origin 5 MU*/vial

*MU : Million Units

**Vial containing 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 powder fraction 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 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**

Not applicable.

9. **SPECIAL WARNING(S), IF NECESSARY**

**Dog:** Vaccination during and after VIRBAGEN OMEGA treatment is contra-indicated, until the dog appears to have recovered.

**Cat:** 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 at 4°C ± 2°C.
Do not freeze.
Store in the original carton.
12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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, 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 leaflet for further information.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC SA
L.I.D. 1ère Avenue - 2065 m
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 AND OTHER SUBSTANCES

Vial containing lyophilisate:

Active substance

Recombinant Omega interferon of feline origin 10 MU*/vial

*MU : Million Units

Vial containing 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 powder fraction 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

Not applicable.

### 9. SPECIAL WARNING(S), IF NECESSARY

**Dog:** Vaccination during and after VIRBAGEN OMEGA treatment is contra-indicated, until the dog appears to have recovered.

**Cat:** 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 at 4°C ± 2°C.

Do not freeze.

Store in the original carton.
12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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, 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 leaflet for further information.

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC SA
L.I.D. 1ère Avenue - 2065 m
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 AND OTHER SUBSTANCES

Vial containing lyophilisate:

Active substance

Recombinant Omega interferon of feline origin 10 MU*/vial

*MU : Million Units

Vial containing 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 powder fraction 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

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

**Dog:** Vaccination during and after VIRBAGEN OMEGA treatment is contra-indicated, until the dog appears to have recovered.

**Cat:** 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 at 4°C ± 2°C.
Do not freeze.
Store in the original carton.
12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC SA  
L.I.D. 1ère Avenue - 2065 m  
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 AND OTHER SUBSTANCES

Vial containing lyophilisate:

Active substance

Recombinant Omega interferon of feline origin 10 MU*/vial

*MU : Million Units

Vial containing 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 powder fraction 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

Not applicable.

9.  SPECIAL WARNING(S), IF NECESSARY

**Dog:** Vaccination during and after VIRBAGEN OMEGA treatment is contra-indicated, until the dog appears to have recovered.

**Cat:** 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 coinfect 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 at 4°C ± 2°C.

Do not freeze.

Store in the original carton.
12. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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, 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 leaflet for further information.

14. **THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”**

Keep out of the reach and sight of children.

15. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC SA  
L.I.D. 1ère Avenue - 2065 m  
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*/ vial

* 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**

Not applicable.

6. **BATCH NUMBER**

Batch number

7. **EXPIRY DATE**

EXP: month/year

8. **THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.
<table>
<thead>
<tr>
<th>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</th>
</tr>
</thead>
</table>

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*/vial

   * 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**

   Not applicable.

6. **BATCH NUMBER**

   Batch number

7. **EXPIRY DATE**

   EXP: month/year

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**

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

VIRBAC SA  
L.I.D. 1ère Avenue - 2065 m  
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)**

**Vial containing lyophilisate:**

**Active substance**

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

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

*MU : Million Units

**Vial containing solvent :**  
Isotonic sodium chloride solution 1 ml

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:
- hyperthermia (3-6 hours after injection)
- vomiting
- soft faeces to mild diarrhoea, in cats only.
In addition, a slight decrease in white blood cells, platelets and red blood cells, and rise in the concentration of alanine aminotransferase may be observed. These parameters return to normal in the week following the last injection.
- transient fatigue during the treatment, in cats only.

If you notice any serious effects or other effects not mentioned in this leaflet, 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 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

Not applicable.
11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport at 4°C ± 2°C.
Do not freeze.
Store in the original carton.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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

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.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.

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 product is available on the website of the European Medicines Agency (EMA) [http://ema.europa.eu](http://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.

België/Belgique/Belgien  
VIRBAC BELGIUM S.A.  
Rue de la station 17  
B-1300 WAVRE  
Tel. : 32 (0) 10 47 06 35

Luxembourg/Luxemburg  
VIRBAC BELGIUM S.A.  
Rue de la station 17  
B-1300 WAVRE  
Tel. : 32 (0) 10 47 06 35

Česká republika  
VIRBAC S.A.

Magyarország  
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Danmark
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Deutschland
VIRBAC Tierarzneimittel GmbH
West Rögen 20
D-23843 Bad Oldesloe
Tel: 49 (4531) 805 555

Eesti
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

España
VIRBAC ESPAÑA S.A.
ES-8950 Esplugues de Llobregat (Barcelona).
Tel.: + 34 93 470 79 40

France
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Ireland
C&M Veterinary Distributors Limited
IE- Limerick
Tel.: 353 61 314 933

Ísland
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Italia
VIRBAC SRL
Via dei Gracchi 30
I-20146 Milano
Tel: 39 02 48 53 451

Körprosz
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Latvija
VIRBAC S.A.

Nederland
VIRBAC NEDERLAND BV
Hermesweg 15
NL-3771 ND - BARNEVELD
Tel: 31 (0) 342 427 100

Norge
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Österreich
VIRBAC Österreich GmbH
A-1180 Wien
Tel: 43 (0) 1 2183426 0

Polska
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Portugal
VIRBAC DE PORTUGAL
LABORATÓRIOS LDA
P-2080-Almeirim
Tél.: (351) 243.570 500

Slovenija
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Slovenská republika
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Suomi/Finland
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Sverige
VIRBAC S.A.
1ère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

United Kingdom
VIRBAC Ltd
lère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

Lietuva
VIRBAC S.A.
lère avenue 2065m – L.I.D.
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

România
VIRBAC S.A.
lère avenue 2065 m – L.I.D
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00

UK-Suffolk IP30 9UP
Tel: 44 (0) 1359 243243

Република България
VIRBAC S.A.
lère avenue 2065 m – L.I.D
F-06516 Carros
Tel: 33 (0) 4 92 08 73 00