

**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*
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10 MU presentation:

Recombinant Omega interferon of feline origin	10 MU*
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\*MU : Million Units

### Solvent:

Isotonic sodium chloride solution	1 ml
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### 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 parvovirus (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 coinfecting 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 parvovirus and in the cat against feline retrovirovirus (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

1<sup>ère</sup> 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 parvovirus (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 coinfecting 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 parvovirus (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 coinfecting 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 parvovirus (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 coinfecting 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 parvovirus (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 coinfecting 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**

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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 parvovirus (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 coinfecting 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.

**België/Belgique/Belgien**  
VIRBAC BELGIUM N.V.  
Esperantolaan 4  
BE-3001 Leuven  
Tel: + 32 (0) 16 38 72 60

**Luxembourg/Luxemburg**  
VIRBAC BELGIUM N.V.  
Esperantolaan 4  
BE-3001 Leuven Belgique / Belgien  
Tel: + 32 (0) 16 38 72 60

**Česká republika**  
VIRBAC  
1ère avenue 2065 m – L.I.D  
FR-06516 Carros Francie  
Tel: + 33 (0) 4 92 08 73 00

**Magyarország**  
VIRBAC HUNGARY KFT  
Szent István krt.11.II/21.  
HU-1055 Budapest  
Tel: +36703387177

**Danmark**  
VIRBAC Danmark A/S  
Profilvej 1  
DK-6000 Kolding  
Tel: + 45 7552 1244

**Malta**  
VIRBAC  
1ère avenue 2065 m – L.I.D  
FR-06516 Carros Franza  
Tel: + 33 (0) 4 92 08 73 00

**Deutschland**  
VIRBAC Tierarzneimittel GmbH  
Rögen 20  
DE-23843 Bad Oldesloe  
Tel: + 49 (4531) 805 111

**Nederland**  
VIRBAC NEDERLAND BV  
Hermesweg 15  
NL-3771 ND-Barneveld  
Tel: + 31 (0) 342 427 127

**Eesti**  
VIRBAC  
1ère avenue 2065 m LID  
FR-06516 Carros Prantsusmaa  
Tel: +33-(0)4 92 08 73 00

**Norge**  
VIRBAC Danmark A/S  
Profilvej 1  
DK-6000 Kolding Danmark  
Tel: + 45 75521244

**Ελλάδα**  
VIRBAC HELLAS A.E.  
13ο χλμ Ε.Ο. Αθηνών - Λαμίας  
EL-14452, Μεταμόρφωση  
Τηλ: +30 2106219520

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

**España**  
VIRBAC ESPAÑA, S.A.  
Angel Guimera 179-181  
ES-08950 - Esplugues de Llobregat (Barcelona)  
Tel: + 34 93 470 79 40

**Polska**  
VIRBAC Sp. z o.o.  
ul. Puławska 314  
PL 02-819 Warszawa  
Tel.: + 48 22 855 40 46

**France**

VIRBAC France  
13ème rue – L.I.D.  
FR-06516 Carros Cedex  
Tél : +33 805 05 55 55

**Ireland**

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

**Ísland**

VIRBAC  
1ère avenue 2065 m – L.I.D  
FR-06516 Carros Frakkland  
Simi: + 33 (0) 4 92 08 73 00

**Italia**

VIRBAC SRL  
Via Ettore Bugatti 15  
IT-20142 Milano  
Tel: + 39 02 40 92 47 1

**Κύπρος**

VIRBAC HELLAS A.E.  
13ο χλμ Ε.Ο. Αθηνών - Λαμίας  
EL-14452, Μεταμόρφωση  
Τηλ.: +30 2106219520

**Latvija**

VIRBAC  
1ère avenue 2065 m LID  
FR-06516 Carros Francjia  
Tel: +33-(0)4 92 08 73 00

**Lietuva**

VIRBAC  
1ère avenue 2065 m LID  
FR-06516 Carros Prancūzija  
Tel: +33-(0)4 92 08 73 00

**România**

VIRBAC  
1ère avenue 2065 m – L.I.D  
FR-06516 Carros Franța  
Tel: + 33 (0) 4 92 08 73 00

**Portugal**

VIRBAC DE PORTUGAL LABORATÓRIOS  
LDA  
R.do Centro Empresarial  
Ed13-Piso 1- Esc.3  
Quinta da Beloura  
PT-2710-693 Sintra  
+ 351 219 245 020

**Slovenija**

VIRBAC  
1ère avenue 2065 m – L.I.D  
FR-06516 Carros Francija  
Tel: + 33 (0) 4 92 08 73 00

**Slovenská republika**

VIRBAC  
1ère avenue 2065 m – L.I.D  
FR-06516 Carros Francúzsko  
Tel: + 33 (0) 4 92 08 73 00

**Suomi/Finland**

VIRBAC  
1ère avenue 2065 m – L.I.D  
FR-06516 Carros Ranska  
Puh/Tel: + 33 (0) 4 92 08 73 00

**Sverige**

VIRBAC DANMARK A/S FILIAL  
SVERIGE,  
c/o Incognito AB,  
Box 1027,  
SE-171 21 Solna  
Tel: + 45 7552 1244

**United Kingdom (Northern Ireland)**

VIRBAC  
1ère avenue 2065m LID  
FR-06516 Carros France  
Tel: + 33-(0)4 92 08 73 00

**Hrvatska**

VIRBAC  
1ère avenue 2065 m – L.I.D  
FR-06516 Carros Francuska  
Tel: + 33 (0) 4 92 08 73 00

**Република България**

VIRBAC  
1ère avenue 2065 m LID  
FR-06516 Carros Франция  
Тел: +33-(0)4 92 08 73 00