

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

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

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

VIRBAGEN OMEGA 5 MU lyophilisate and solvent for suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose of 1 ml contains:

Lyophilisate:

Interferon omega, recombinant, feline                      5 MU\*

\*MU: Million Units

**3. PACKAGE SIZE**

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

**4. TARGET SPECIES**

Dogs and cats.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Dogs: Intravenous use

Cats: Subcutaneous use

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use immediately.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.

Do not freeze.

Store in the original package.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC

**14. MARKETING AUTHORISATION NUMBERS**

Vm 05653/5022

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS**

**LYOPHILISATE VIAL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Virbagen Omega



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

5 MU

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp: {mm/yyyy}

Once reconstituted use immediately.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS**

**SOLVENT VIAL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Virbagen Omega solvent



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

1 ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

EXP: {mm/yyyy}

## **B. PACKAGE LEAFLET**

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

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

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

**2. Composition**

Each dose of 1ml contains:

**Active substance:**

Lyophilisate:

5 MU presentation:

Interferon omega, recombinant, feline 5 MU\*

10 MU presentation:

Interferon omega, recombinant, feline 10 MU\*

\*MU: Million Units

Lyophilisate: white colour

Solvent: colourless liquid

**3. Target species**

Dogs and cats.

**4. Indications for use**

Dogs:

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

Cats:

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

- a reduction of clinical signs during the symptomatic phase (4 months)

- a reduction of mortality:

- in anaemic cats, mortality rate of about 60% at 4, 6, 9 and 12 months was reduced by approximately 30% following treatment with interferon.

- in non-anaemic cats, mortality rate of 50% in cats infected by FeLV was reduced by 20% following treatment with interferon. In cats infected by FIV, mortality was low (5%) and was not influenced by the treatment.

## **5. Contraindications**

Dogs: Vaccination during and after treatment with this veterinary medicinal product is contraindicated, until the dog appears to have recovered.

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

## **6. Special warnings**

### Special warnings:

No information on the induction of long-term adverse reactions is available in dog and cat, especially for autoimmune disorders. Such adverse 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 veterinary medicinal 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 safe use in the target species:

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

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

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

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

### Pregnancy and lactation:

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

Interaction with other medicinal products and other forms of interaction:

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

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

Overdose:

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

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

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

Major incompatibilities:

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

**7. Adverse events**

Dogs:

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

<sup>1</sup>Slight, Return to normal in the week following the last injection.

<sup>2</sup>Slight and Transient.

<sup>3</sup>3-6 hours after injection.

Cats:

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

<sup>1</sup>Slight, Return to normal in the week following the last injection.

<sup>2</sup>Slight and Transient.

<sup>3</sup>3-6 hours after injection.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

Dogs: The dose is 2.5 MU/kg bodyweight.

Cats: The dose is 1 MU/kg bodyweight.

Dogs: The reconstituted veterinary medicinal product should be injected intravenously once daily for 3 consecutive days.

Cats: The reconstituted veterinary medicinal 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 veterinary medicinal product should be used immediately after reconstitution.

## **9. Advice on correct administration**

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

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

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Store in the original carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the package and the vial label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Virbagen Omega 5 MU: Vm 05653/5022

Virbagen Omega 10 MU: Vm 05653/5021

For the 5 MU presentation:

Cardboard box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

For the 10 MU presentation:

Cardboard box containing 1 vial of lyophilisate and 1 vial with 1 ml of solvent

Cardboard box containing 2 vials of lyophilisate and 2 vials with 1 ml of solvent

Cardboard box containing 5 vials of lyophilisate and 5 vials with 1 ml of solvent

Not all pack sizes may be marketed.

**15. PID link (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

**16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC  
1<sup>ère</sup> Avenue 2065m LID  
06516 CARROS  
France

Local representatives and contact details to report suspected adverse reactions:

Virbac Ltd  
Suffolk, IP30 9UP – UK  
Tel: +44 (0)-1359 243243

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

**17. Other information**

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