ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soligental 3000 IU/ml eye drop solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance:
Gentamicin ..... 3000 IU
(as gentamicin sulfate)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Trometamol	
Disodium edetate	5 mg
Parahydroxybenzoic acid	0.90 mg
Sodium hydroxide (for pH adjustment)	
Sodium chloride	
Hypromellose	
Povidone	
Water for injections	

Sterile aqueous solution.
Slightly yellow to yellow-green solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

In dogs and cats:
Curative treatment of bacterial conjunctivitis and keratoconjunctivitis due to sensitive gentamicin bacteria, as supported by an antibiotic sensitivity assay.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, other aminoglycosides or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

To prevent any contamination of the solution, stop close the container after use.

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

People with known hypersensitivity to aminoglycosides should avoid contact with the veterinary medicinal product.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats and dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Application site reaction (conjunctival irritation)[1]

[1] At the onset of treatment, very slight, always transitory and disappears spontaneously without any specific treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Gentamicin crosses the placenta barrier and can, therefore, induce toxic effects in the foetus when very high dosages are given to the dams. The veterinary medicinal product is an ophthalmic solution and the systemic absorption of gentamicin could be negligible. Therefore, the product could be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Ocular use.
900 IU of gentamicin / day for 8 days i.e. two drops instilled 3 times a day for 8 days.
Instil the solution in the lower conjunctival sac using the dosing device.

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

In case of overdose, the regeneration of the cornea epithelium can be delayed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QS01AA11

4.2 Pharmacodynamics

Gentamicin is a bactericide antibiotic belonging to the aminoglycoside family. Its acts by inhibiting affecting protein synthesis in bacteria. It is active on Gram-positive and Gram-negative bacteria, particularly on *Pseudomonas* and *Staphylococcus.*

Clinical breakpoints which concern canine *Pseudomonas aeruginosa* towards gentamicin are proposed by the CLSI in the M31-A3 guidance. The clinical breakpoints have been set as follows:

Method of testing	Susceptible	Intermediary	Resistant
Diffusion method with disks containing 10 µg of gentamicin	$\geq$16 mm	13-15 mm	$\leq$ 12 mm
Dilution method	$\leq$2 (µg/mL)	4 (µg/mL)	$\geq$ 8 (µg/mL)

4.3 Pharmacokinetics

The application of one drop enables the persistence of therapeutic levels for more than 6 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 15 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Coloured brown vial, type I
Chlorobutytl dropper (blue)
Chlorobutyl High-density polyethylene stopper

Pack size:
Cardboard box with 1 x 5 ml multidose vial.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soligental 3000 IU/ml eye drop solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Gentamicin (as gentamicin sulfate)..... 3000 IU

3. PACKAGE SIZE

5 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Ocular use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 15 days.

9. SPECIAL STORAGE PRECAUTIONS

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

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soligental

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3000 IU/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Soligental 3000 IU/ml eye drop solution

2. Composition

Each ml contains:

Active substance:
Gentamicin ..... 3000 IU
(as gentamicin sulfate)

Excipients:
Disodium edetate..... 5 mg
Parahydroxybenzoic acid ..... 0.90 mg

Sterile aqueous solution.
Slightly yellow to yellow-green solution.

3. Target species

Dogs and cats.

4. Indications for use

In dogs and cats:
Curative treatment of bacterial conjunctivitis and keratoconjunctivitis due to sensitive gentamicin bacteria, as supported by an antibiotic sensitivity assay.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, other aminoglycosides or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
To prevent any contamination of the solution, stop close the container after use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to aminoglycosides should avoid contact with the veterinary medicinal product.
Wash hands after use.

Pregnancy and lactation:

Gentamicin crosses the placenta barrier and can, therefore, induce toxic effects in the foetus when very high dosages are given to the dams. The veterinary medicinal product is an ophthalmic solution and the systemic absorption of gentamicin could be negligible. Therefore, the product could be used during pregnancy and lactation.

Overdose:
In case of overdose, the regeneration of the cornea epithelium can be delayed.

7. Adverse events

Cats and dogs:

Rare (1 to 10 animals / 10,000 animals treated):
Application site reaction (conjunctival irritation) [1]

[1] At the onset of treatment, very slight, always transitory and disappears spontaneously without any specific treatment.

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

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

Ocular use.
900 IU of gentamicin / day for 8 days i.e. two drops instilled 3 times a day for 8 days.

9. Advice on correct administration

Instil the solution in the lower conjunctival sac using the dosing device.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the vial.

Shelf life after first opening the immediate packaging: 15 days.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Cardboard box with 1 x 5 ml multidose vial.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing Authorisation Holder and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065m LID
06516 Carros
FRANCE

Manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065m LID
06516 Carros
FRANCE

Or

LABIANA LIFE SCIENCES, S.A
C/ Venus, 26, Pol. Ind. Can Parellada Terrassa
08228 Barcelona
SPAIN

Local representatives and contact details to report suspected adverse reactions:

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