[Version 9,10/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFELAB 40 mg/ml solution for injection for cattle, pigs, cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Tolfenamic acid 40.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E 1519)	10.4 mg
Sodium formaldehyde sulfoxylate	5.0 mg
Diethylene glycol monoethylether	
Ethanolamine	
Solvent:	
Water for injections	

Clear, yellowish solution for injection, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, cats and dogs.

3.2 Indications for use for each target species

Supportive treatment of conditions that can cause pain and inflammation:

- **Cattle:** as an adjunct in the reduction of acute inflammation associated with respiratory diseases and as an adjunct in the treatment of acute mastitis.

- **Pigs:** as an adjunct in the treatment of Postpartum Dysgalactia Syndrome (PDS).

- **Cats:** as an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate.

- **Dogs:** for the treatment of inflammatory and painful postoperative syndromes and for the reduction of postoperative pain.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any excipient.
Do not use in animals with cardiac disease, impaired hepatic function or acute renal insufficiency.
Do not use in case of ulceration or digestive bleeding or in case of blood dyscrasia.
Do not inject intramuscularly in cats.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in animals less than 6 weeks of age, or in aged animals, may involve additional risk. If such a use cannot be avoided animals may require a reduced dosage and careful clinical management is essential. Reduced metabolism and excretion in these animals should be considered.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
Concurrent administration of potential nephrotoxic drugs should be avoided.
It is preferable that the product is not administered to animals undergoing general anaesthesia until fully recovered.
In case of undesirable effects (anorexia, vomiting, diarrhoea, presence of blood in faeces) occurring during the treatment, your veterinarian should be contacted for advice and the possibility of stopping treatment should be considered.
In dogs, the scale of pain relief after pre-operative administration may be influenced by the severity and duration of the operation.
In cattle and pigs the administration of this medicinal product in the neck muscles is recommended, since these have a greater local tolerance.

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

The product may cause skin and eye sensitisation. People with known hypersensitivity to non-steroidal anti-inflammatory (NSAIDs) or to benzyl alcohol should avoid contact with the veterinary medicinal product.
Administer the veterinary medicinal product with caution to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
The product may cause skin and eye irritation. Avoid contact with skin or eyes. In case of accidental contact, wash immediately exposed area with plenty of clean water.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Pigs, cats and dogs.

Rare	Polyuria, polydipsia[1]

(1 to 10 animals / 10,000 animals treated):	
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Local injection site reactions. Anorexia[2] Diarrhoea, vomiting and blood in faeces[2]

1- these signs cease spontaneously after treatment.
2- where either persists, treatment should be discontinued.

Target species: Cattle

Rare (1 to 10 animals / 10,000 animals treated):	Collapse[3] Polyuria, polydipsia[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Local injection site reactions. Anorexia[2] Diarrhoea, vomiting and blood in faeces[2]

1- these signs cease spontaneously after treatment.
2- where either persists, treatment should be discontinued.
3- after rapid intravenous injection.

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Cats and dogs:
The safety of the veterinary medicinal product has not been established in cats and dogs during pregnancy and lactation.
The use is not recommended during pregnancy or lactation.

Cattle and pigs:
The results of the studies carried out in the rat and in the rabbit showed no teratogenic effect.
Peri and postnatal studies performed in the rat showed that tolfenamic acid has no influence on the evolution of viability, the gestation index or the appearance of malformations.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer with other non-steroidal anti-inflammatory drugs simultaneously or with an interval of 24 hours between them. Other NSAIDs, diuretics, anticoagulants and substances with high affinity to plasma proteins may compete for binding and produce toxic effects.
Do not administer in conjunction with anticoagulants.
Avoid simultaneous administration of potentially nephrotoxic drugs.
Do not administer in conjunction with glucocorticoids.

3.9 Administration routes and dosage

Cattle: intramuscular (IM) or intravenous (IV) use.
Pigs: intramuscular (IM) use.
Dogs: intramuscular (IM) or subcutaneous (SC) use.
Cats: subcutaneous (SC) use.

- **Cats and dogs:** 4 mg tolfenamic acid/kg bodyweight, equivalent to 1 ml veterinary medicinal product/10 kg bodyweight, given as a single injection and repeated once after 24 hours if required and depending upon clinical assessment.
For the reduction of post-operative pain in dogs, this is best given pre-operatively, at the time of premedication, as a single dose, one hour before induction of anaesthesia.
In low-weight animals, it is advisable to use insulin-type syringes to ensure correct dosing.

- **Cattle:** For use as an adjunct in the reduction of acute inflammation associated with respiratory disease in cattle: 2 mg of tolfenamic acid/kg bodyweight, equivalent to 1 ml of veterinary medicinal product/20 kg bodyweight by intramuscular injection into the neck area. Treatment may be repeated once after 48 hours.
The maximum injected volume is 20 ml per injection site.
For use as an adjunct in the treatment of acute mastitis in mastitis: 4 mg of tolfenamic acid/kg bodyweight, equivalent to 1ml of veterinary medicinal product/10 kg bodyweight as a single intravenous injection.
When administering intravenously, the product should be injected slowly. At the first signs of intolerance, the injection should be interrupted.

- **Pigs:** 2 mg tolfenamic acid/kg bodyweight, equivalent to 1 ml of veterinary medicinal product/20kg bodyweight as a single intramuscular injection.
The maximum injected volume is 20 ml per injection site.

The rubber stopper of the vial may be safely punctured up to 84 times.

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

The studies of tolerance in bovines allowed to define that a dose 4 times superior to the therapeutic one (16 mg / kg body weight) can constitute the margin of safety of administration of the product.
At doses of 18 and 20 mg / kg bodyweight (4.5 and 5 times the therapeutic dose), signs of toxicity were recorded transiently in the central level, in the form of agitation, balance disorders, and motor incoordination.
There were significant variations in the haematological and biochemical parameters that corresponded to transient modifications of the digestive and hepatic functions.

In pigs, tolfenamic acid is well tolerated (up to 5 times higher than the therapeutic dose), although there may be reactions at the injection site that are intense and spontaneous recovery in 7-14 days.
In case of overdosage in dogs and cats, the symptoms described in the section on adverse reactions may appear exacerbated. In case it is recommended to suspend the treatment and establish a symptomatic treatment.

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

Exclusive administration by the veterinarian in the case of intravenous administration or under his supervision and control.

3.12 Withdrawal periods

Cattle:
Intramuscular injection
Meat and offal: 12 days.
Milk: zero hours
Intravenous injection
Meat and offal: 4 days.
Milk: 24 hours.

Pigs:
Meat and offal: 16 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AG02.

4.2 Pharmacodynamics

Tolfenamic acid (N-(2-methyl-3-chlorophenyl) anthranilic acid) is a non-steroidal anti-inflammatory drug belonging to the fenamate group. Tolfenamic acid possesses anti-inflammatory, analgesic and antipyretic properties.
The anti-inflammatory activity of tolfenamic acid is due to inhibition of cyclooxygenase (COX-1 and COX-2) leading to a reduction in prostaglandin (important inflammatory mediators) and thromboxane (platelet aggregators).

4.3 Pharmacokinetics

In cattle and pigs, tolfenamic acid, administered by intramuscular route at a dose of 2 mg/kg b.w., is rapidly absorbed from the injection site, reaching maximum mean plasma concentrations of around 1.4 µg/ml in cattle and 2.3 µg/ml in pigs in approximately 1 hour, with a volume of distribution of about 1.3 L/kg in both species and a plasma albumin binding > 97%.

In dogs, tolfenamic acid is easily absorbed. After parenteral administration of a dose of 4 mg/kg b.w. a maximum plasma concentration of about 4 µg/ml (SC) and about 3 µg/ml (IM) is obtained after two hours.
In cats, the absorption is rapid. After one hour of parenteral administration of 4 mg/kg b.w., a peak of 3.9 µg/ml is recorded.

Tolfenamic acid is distributed in all organs with a higher concentration in plasma, digestive tract, liver, lungs and kidneys, being on the contrary very weak in brain. Tolfenamic acid and its metabolites cross the placenta in a small proportion.
In extracellular fluids, concentrations are similar to those of plasma in both healthy and inflamed peripheral tissues.
It also appears in milk in active form, mainly associated with the curds.
Tolfenamic acid follows an enterohepatic cycle that ensures a longer duration of therapeutic concentration in plasma.
The elimination half-life of tolfenamic acid varies between 3-5 hours in pigs and 8-15 hours in cattle.

It is excreted fundamentally unaltered by urinary (~70%), biliary and fecal (~30%) in pigs and cattle. The milk excretion is negligible.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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: 28 days.

5.3 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Nature of the container
Amber type II glass vials of 20 ml, 50 ml, 100 ml and 250 ml, closed with chlorobutyl stoppers and aluminium caps.

Pack sizes
Box with 1 vial of 20 ml
Box with 1 vial of 50 ml
Box with 1 vial of 100 ml
Box with 1 vial of 250 ml
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Labiana Life Sciences, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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 with vial(s) of 20 ml, 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFELAB 40 mg/ml solution for injection for cattle, pigs, cats and dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tolfenamic acid 40.0 mg

3. PACKAGE SIZE

20 ml
50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs, cats and dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cats: SC
Dogs: IM and SC
Cattle: IM and IV
Pigs: IM

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Intramuscular injection
Meat and offal: 12 days
Milk: zero hours
Intravenous injection
Meat and offal: 4 days
Milk: 24 hours

Pigs:
Meat and offal: 16 days

8. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Use by: ….

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

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

Labiana Life Sciences, S.A.

14. MARKETING AUTHORISATION NUMBERS

XXXXXX

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFELAB 40 mg/ml solution for injection for cattle, pigs, cats and dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Tolfenamic acid 40.0 mg

3. TARGET SPECIES

Cattle, pigs, cats and dogs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Intramuscular injection
Meat and offal: 12 days
Milk: zero hours
Intravenous injection
Meat and offal: 4 days
Milk: 24 hours

Pigs:
Meat and offal: 16 days

6. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Use by: ….

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml and 50 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFELAB 40 mg/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Tolfenamic acid 40.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Use by: ….

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

TOLFELAB 40 mg/ml solution for injection for cattle, pigs, cats and dogs

2. Composition

Each ml contains:

Active substance:	
Tolfenamic acid	40.0 mg
Excipients:	
Benzyl alcohol (E 1519)	10.4 mg
Sodium formaldehyde sulfoxylate	5.0 mg

Clear, yellowish solution, free from visible particles.

3. Target species

Cattle, pigs, cats and dogs.

4. Indications for use

Supportive treatment of conditions that can cause pain and inflammation:

Cattle: as an adjunct in the reduction of acute inflammation associated with respiratory diseases and as an adjunct in the treatment of acute mastitis.

Pigs: as an adjunct in the treatment of Postpartum Dysgalactia Syndrome (PDS).

Cats: as an adjunct in the treatment of upper respiratory disease in association with antimicrobial therapy, if appropriate.

Dogs: for the treatment of inflammatory and painful postoperative syndromes and for the reduction of postoperative pain.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any excipient.
Do not use in animals with cardiac disease, impaired hepatic function or acute renal insufficiency.
Do not use in case of ulceration or digestive bleeding or in case of blood dyscrasia.
Do not inject intramuscularly in cats.

6. Special warnings

Special precautions for safe use in the target species:
Use in animals less than 6 weeks of age, or in aged animals, may involve additional risk. If such a use cannot be avoided animals may require a reduced dosage and careful clinical management is essential. Reduced metabolism and excretion in these animals should be considered.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Concurrent administration of potential nephrotoxic drugs should be avoided.
It is preferable that the product is not administered to animals undergoing general anaesthesia until fully recovered.
In case of undesirable effects (anorexia, vomiting, diarrhoea, presence of blood in faeces) occurring during the treatment, your veterinarian should be contacted for advice and the possibility of stopping treatment should be considered.
In dogs, the scale of pain relief after pre-operative administration may be influenced by the severity and duration of the operation.
In cattle and pigs, the administration of this medicinal product in the neck muscles is recommended, since these have a greater local tolerance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product may cause skin and eye sensitisation. People with known hypersensitivity to non-steroidal anti-inflammatory (NSAIDs) or to benzyl alcohol should avoid contact with the veterinary medicinal product.
Administer the veterinary medicinal product with caution to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
The product may cause skin and eye irritation. Avoid contact with skin or eyes. In case of accidental contact, wash immediately exposed area with plenty of clean water.

Pregnancy and lactation:
Cats and dogs:
The safety of the veterinary medicinal product has not been established in cats and dogs during pregnancy and lactation.
The use is not recommended during pregnancy or lactation.

Cattle and pigs:
The results of the studies carried out in the rat and in the rabbit showed no teratogenic effect.
Peri and postnatal studies performed in the rat showed that tolfenamic acid has no influence on the evolution of viability, the gestation index or the appearance of malformations.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not administer with other non-steroidal anti-inflammatory drugs simultaneously or with an interval of 24 hours between them. Other NSAIDs, diuretics, anticoagulants and substances with high affinity to plasma proteins may compete for binding and produce toxic effects.
Do not administer in conjunction with anticoagulants.
Avoid simultaneous administration of potentially nephrotoxic drugs.
Do not administer in conjunction with glucocorticoids.

Overdose:
The studies of tolerance in bovines allowed to define that a dose 4 times superior to the therapeutic one (16 mg / kg body weight) can constitute the margin of safety of administration of the product.
At doses of 18 and 20 mg / kg bodyweight (4.5 and 5 times the therapeutic dose), signs of toxicity were recorded transiently in the central level, in the form of agitation, balance disorders, and motor incoordination.
There were significant variations in the haematological and biochemical parameters that corresponded to transient modifications of the digestive and hepatic functions.

In pigs, tolfenamic acid is well tolerated (up to 5 times higher than the therapeutic dose), although there may be reactions at the injection site that are intense and spontaneous recovery in 7-14 days.
In case of overdosage in dogs and cats, the symptoms described in the section on adverse reactions may appear exacerbated. In case it is recommended to suspend the treatment and establish symptomatic treatment.

Special restrictions for use and special conditions for use:
Exclusive administration by the veterinarian in the case of intravenous administration or under his supervision and control.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Target species: Pigs, cats and dogs.

Rare (1 to 10 animals / 10,000 animals treated):	Polyuria, polydipsia[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Local injection site reactions. Anorexia[2] Diarrhoea, vomiting and blood in faeces[2]

1- these signs cease spontaneously after treatment.
2- where either persists, treatment should be discontinued.

Target species: Cattle

Rare (1 to 10 animals / 10,000 animals treated):	Collapse[3] Polyuria, polydipsia[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Local injection site reactions. Anorexia[2] Diarrhoea, vomiting and blood in faeces[2]

1- these signs cease spontaneously after treatment.
2- where either persists, treatment should be discontinued.
3- after rapid intravenous 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 {national system details}.

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

Cattle: intramuscular (IM) or intravenous (IV) use.
Pigs: intramuscular (IM) use.
Dogs: intramuscular (IM) or subcutaneous (SC) use.
Cats: subcutaneous (SC) use.

Cats and dogs: 4 mg tolfenamic acid/kg bodyweight, equivalent to 1 ml veterinary medicinal product/10 kg bodyweight, given as a single injection and repeated once after 24 hours if required and depending upon clinical assessment.
For the reduction of post-operative pain in dogs, this is best given pre-operatively, at the time of premedication, as a single dose, one hour before induction of anaesthesia.
In low-weight animals, it is advisable to use insulin-type syringes to ensure correct dosing.

Cattle: For use as an adjunct in the reduction of acute inflammation associated with respiratory disease in cattle, 2 mg of tolfenamic acid/kg bodyweight, equivalent to 1 ml of veterinary medicinal product/20 kg bodyweight by intramuscular injection into the neck area. Treatment may be repeated once after 48 hours. The maximum injected volume is 20 ml per injection site.
For use as an adjunct in the treatment of acute mastitis, 4 mg of tolfenamic acid/kg bodyweight, equivalent to 1ml of veterinary medicinal product/10 kg bodyweight as a single intravenous injection.
When administering intravenously, the product should be injected slowly. At the first signs of intolerance, the injection should be interrupted.

Pigs: 2 mg tolfenamic acid/kg bodyweight, equivalent to 1 ml of veterinary medicinal product/20kg bodyweight as a single intramuscular injection. The maximum injected volume is 20 ml per injection site.

9. Advise on correct administration

The rubber stopper of the vial may be safely punctured up to 84 times.

10. Withdrawal periods

Cattle:
Intramuscular injection
Meat and offal: 12 days
Milk: zero hours

Intravenous injection
Meat and offal: 4 days
Milk: 24 hours

Pigs:
Meat and offal: 16 days

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of in wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. 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

MA number:

Pack sizes
Box with 1 vial of 20 ml
Box with 1 vial of 50 ml
Box with 1 vial of 100 ml
Box with 1 vial of 250 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Labiana Life Sciences S.A. - Venus 26 - 08228 Terrassa (Barcelona) - Spain.

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