[Version 9,03/2022]corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veterelin 4 microgram/ml solution for injection for cattle, horses, pigs and rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Buserelin .....4 microgram
(equivalent to 4.2 microgram buserelin acetate)

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)	20 mg
Sodium chloride	
Sodium dihydrogen phosphate monohydrate	
Sodium hydroxide	
Water for injection	

Clear and colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cows), horses (mares), rabbits (adult females) and pigs (sows, gilts).

3.2 Indications for use for each target species

Cattle (cows):
- Treatment of infertility associated with follicular cysts.
- Induction and synchronisation of oestrus and ovulation in combination with prostaglandin F2α (PGF2α) or its analogues, with or without progestogens, as part of a timed artificial insemination protocol.
- Improvement in conception and / or pregnancy rates in cows with low fertility during the luteal phase following artificial insemination.

Horses (mares):
- Induction of ovulation and improvement of conception and / or pregnancy rates.

Pigs (sows, gilts):
- Induction of ovulation following oestrus synchronisation as part of an insemination program.

Rabbits (adult females):
- Induction of ovulation and improvement in conception rates.

3.3 Contraindications

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

3.4 Special warnings

Treatment with a GnRH analogue does not eliminate the underlying cause(s) of the fertility disorder.

Residues of alcohol and disinfectants may affect the activity of buserelin. Therefore, care should be taken to ensure that skin and/or stopper of the vial are completely dry after disinfection before piercing.

Cattle (cows):
Cattle with a short interval between calving and insemination (< 60 days), low body condition score or high parity may have a lower pregnancy rate after a standard synchronization protocol (see section 3.9). There is no guarantee that all cows synchronized according to protocol will be in oestrus at the time of artificial insemination. The chances of conception may be higher if the cow is in oestrus at the time of insemination.

Pigs (sows, gilts):
The presence of a boar at the time of artificial insemination is recommended.
Animals should be checked for signs of oestrus before insemination.
A negative energy balance during lactation may be associated with mobilization of body reserves resulting in a sharp decrease in the thickness of the fat on the back (more than about 30%). In these animals, oestrus and ovulation may be delayed, and these animals should be cared for and bred on an individual basis.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Infection may occur if anaerobic bacteria penetrate tissue at the injection site, in particular following intramuscular injection. Use aseptic techniques when injecting the veterinary medicinal product.

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

Buserelin may affect reproductive function, as it has been shown to be foetotoxic in laboratory animals.

Women of childbearing age should handle this veterinary medicinal product with caution. Pregnant women should not administer this veterinary medicinal product.

When administering the veterinary medicinal product, care should be taken to avoid eye and skin contact or accidental self-injection.

In case of accidental eye contact, rinse thoroughly with water. Should skin contact with the veterinary medicinal product occur, wash exposed area immediately with soap and water. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

People with known hypersensitivity to GnRH analogues, benzyl alcohol or any of the excipients should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment

Not applicable

3.6 Adverse events

Cattle (cows), horses (mares), pigs (sows, gilts), rabbits (adult females):

None known.

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:
The safety of the veterinary medicinal product has not been established during all stages of pregnancy in the target animal species.
The veterinary medicinal product is indicated for use in female animals at or close to the time of mating or insemination, and as such, use during the luteal phase (after ovulation) is considered safe for use in lactating and non-lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Routes of administration:

Cattle, horses and rabbits: intramuscular, intravenous or subcutaneous use.
Pigs: intramuscular or intravenous use.

The vial can only be broached a maximum of 20 times. When treating groups of animals at the same time, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.

Dosage:
Cattle (cows): Depending on the indication, a single dose of 10 mcg buserelin per animal (corresponding to 2.5 ml of the veterinary medicinal product) or 20 mcg buserelin per animal (corresponding to 5.0 ml of the veterinary medicinal product).

Horses (mares): A single dose of 40 mcg buserelin per animal (corresponding to 10 ml of the veterinary medicinal product).

Pigs (sows, gilts): A single dose of 10 mcg buserelin per animal (corresponding to 2.5 ml of the veterinary medicinal product).

Rabbits (adult females): A single dose of 0.8 mcg buserelin per animal (corresponding to 0.2 ml of the veterinary medicinal product).

Protocols for use:

Cattle (cows)
Treatment of infertility associated with follicular cysts:
Administer a single dose of 20 mcg buserelin per animal.
A response to treatment is expected within 10-14 days. If a palpable corpus luteum does not develop, or a new cyst forms, the treatment should be repeated. Insemination should be performed at the first oestrus after treatment.

Induction and synchronisation of oestrus and ovulation in combination with prostaglandin F2α (PGF2α) or its analogues, with or without progestogens, as part of a timed artificial insemination protocol:
Judgement on the protocol should be chosen by the responsible veterinarian, on the basis of the intended objective and characteristics of the individual herd or animal. The following protocols have been evaluated and could be used:

In cyclic cows:
Day 0: Administer a single dose of 10 mcg buserelin per animal.
Day 7: Administer prostaglandin or analogue (at luteolytic dosage).
Day 9: Administer a single dose of 10 mcg buserelin per animal.
Artificial insemination 16 to 24 hours after the second (buserelin) injection of this veterinary medicinal product or at the time of oestrus, if earlier.

In cyclic and non-cyclic cows:
Day 0: Administer a single dose of 10 mcg buserelin per animal and insert a progestogen-releasing insert.
Day 7: Remove the progestogen-releasing insert and administer prostaglandin or its analogue (at luteolytic dosage).
Day 9: Administer a single dose of 10 mcg buserelin per animal.
Artificial insemination 16 to 24 hours after the second (buserelin) injection of this veterinary medicinal product or at the time of oestrus, if earlier.

Alternatively:
Day 0: Administer a single dose of 10 mcg buserelin per animal and insert a progestogen-releasing insert.
Day 7: Remove the progestogen-releasing insert and administer prostaglandin or its analogue (at luteolytic dosage) and PMSG (400 – 500 IU).
Day 9: Administer a single dose of 10 mcg buserelin per animal.
Artificial insemination 16 to 24 hours after the second (buserelin) injection of this veterinary medicinal product or at the time of oestrus, if earlier.

Improvement in conception and / or pregnancy rates in cows with low fertility, during the luteal phase following artificial insemination:
Administer a single dose of 10 mcg buserelin per animal 11 - 13 days after insemination.

Horses (mares)
Induction of ovulation and improvement in conception and / or pregnancy rates:
Administer a single dose of 40 mcg buserelin per animal on the first day that the follicle reaches its optimal size (as determined by previous clinical history and transrectal examinations).
Ovulation usually occurs within 24 - 36 hours after treatment; if the mare has not ovulated during this period, administration should be repeated.

Pigs (sows, gilts)
Induction of ovulation following oestrus synchronisation as part of an insemination program

Gilts: Administer a single dose of 10 mcg buserelin per animal between 115 - and 120 - hours following oestrus synchronization with a progestogen. A single artificial insemination should be performed 30 - 33 hours after administration of the veterinary medicinal product.
Sows: Administer a single dose of 10 mcg buserelin per animal 83 - 89 hours after weaning. A single artificial insemination should be performed 30 - 33 hours after administration of the veterinary medicinal product.
In individual cases, oestrus may not be visible 30 - 33 hours after treatment with the veterinary medicinal product. In such cases, insemination can be carried out later, at a time when oestrus symptoms are present.

Rabbits (adult females)
Induction of ovulation and improvement in conception rates:
Administer a single dose of 0.8 mcg buserelin per animal at the time of mating or insemination.
For post-partum insemination, administer a single dose of 0.8 mcg buserelin no less than 24 hours post-partum, followed immediately by insemination.

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

None known.

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

Cattle, horses
Meat and offal: Zero days.
Milk: Zero hours.

Pigs, rabbits
Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCVet Code: QH01CA90

4.2 Pharmacodynamics

Buserelin is a peptide hormone which is chemically analogous to the releasing hormone of luteinising hormone (LH) and follicle stimulating hormone (FSH), and therefore is a gonadotrophin releasing hormone (GnRH) analogue.
The mode of action of the veterinary medicinal product corresponds to the physiological action of naturally occurring GnRH. GnRH leaves the hypothalamus via the hypophyseal portal vessels and enters the anterior lobe of the hypophysis where it induces the secretion of the gonadotrophins FSH and LH into the peripheral blood stream. These then act to cause maturation of ovarian follicles, ovulation and luteinisation in the ovary.

4.3 Pharmacokinetics

After parenteral administration, buserelin is rapidly absorbed and excreted, mainly via the urine. Metabolism takes place in the liver, kidneys and pituitary gland. All metabolites are small, inactive peptides.

Cattle, horses and rabbits:
After buserelin injection, C_{max} is reached after one hour. Administration of quantities higher than those clinically recommended do not stimulate increased secretion of LH and FSH. Six hours after administration, plasma concentration of buserelin returns to baseline levels.

Pigs:
After administration of buserelin, C_{max} was reached at 1.7 hours.

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

Do not store above 25ºC.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless glass vial of 10 or 20 or 100 ml, closed with a grey type I bromobutyl rubber stopper and aluminium cap with blue polypropylene flip-off top.'

Pack sizes:
Cardboard box containing 1 vial of 10 ml
Cardboard box containing 1 vial of 20 ml
Cardboard box containing 5 vials of 10 ml
Cardboard box containing 1 vial of 100 ml

Not all pack sizes may be marketed.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

Cardboard box containing one 10 ml vial
Cardboard box containing one 20 ml vial
Cardboard box containing 5 vials of 10 ml.
Cardboard box containing one 100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veterelin 4 microgram/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Buserelin ..... 4 microgram/ml
(equivalent to 4.2 microgram of buserelin acetate)

3. PACKAGE SIZE

1 x 10 ml
1 x 20 ml
5 x 10 ml
1 x 100 ml

4. TARGET SPECIES

Cattle (cows), horses (mares), rabbits (adult females) and pigs (sows, gilts) .

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle, horses and rabbits: intramuscular, intravenous or subcutaneous use.
Pigs: intramuscular or intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle, horses
Meat and offal: Zero days.
Milk: Zero hours.

Pigs, rabbits
Meat and offal: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS

Adhesive label for 10 ml or 20 ml vial.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veterelin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Buserelin ..... 4 microgram/ml
(equivalent to 4.2 microgram of buserelin acetate)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.
Once opened use by: _____

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Adhesive label for 100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Veterelin 4 microgram/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Buserelin ..... 4 microgram/ml
(equivalent to 4.2 microgram of buserelin acetate)

3. TARGET SPECIES

Cattle (cows), horses (mares), rabbits (adult females) and pigs (sows, gilts) .

4. ROUTES OF ADMINISTRATION

Cattle, horses and, rabbits: intramuscular, intravenous or subcutaneous use.
Pigs: intramuscular or intravenous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle, horses
Meat and offal: Zero days.
Milk: Zero hours.

Pigs, rabbits
Meat and offal: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.
Once opened use by: _____

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Veterelin 4 microgram/ml solution for injection for cattle, pigs, horses, and rabbits

2. Composition

Each ml contains:

Active substances:
Buserelin .....4 microgram
(equivalent to 4.2 microgram of buserelin acetate)

Excipients:
Benzyl alcohol (E 1519) ……... 20 mg

Clear and colourless solution.

3. Target species

Cattle (cows), horses (mares), rabbits (adult females) and pigs (sows, gilts).

4. Indications for use

Cattle (cows):

- Treatment of infertility associated with follicular cysts.
- Induction and synchronization of oestrus and ovulation in combination with prostaglandin F2α (PGFα) or its analogues, with or without progestogens, as part of a timed artificial insemination protocol.
- Improvement in conception and / or pregnancy rate in cows with low fertility, during the luteal phase following artificial insemination.

Horses (mares):

- Induction of ovulation and improvement in conception and / or pregnancy rates.

Pigs (sows, gilts):

- Induction of ovulation following oestrus synchronization as part of an insemination program.

Rabbits (adult females):

- Induction of ovulation and improvement in conception rates.

5. Contraindications

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

6. Special warnings

Special warnings:
Treatment with a GnRH analogue, such as buserelin, does not eliminate the underlying cause(s) of the fertility disorder.

Residues of alcohol and disinfectants may affect the activity of buserelin. Therefore, care should be taken to ensure that skin and / or stopper of the vial are completely dry after disinfection before piercing.

Cattle (cows):
Cattle with a short interval between calving and insemination (< 60 days), low body condition score or high parity may have a lower pregnancy rate after a standard synchronization protocol (see information under Dosage for each species, routes and method of administration).
There is no guarantee that all cows synchronized according to protocol will be in oestrus at the time of artificial insemination. The chances of conception may be higher if the cow is in oestrus at the time of insemination.

Pigs (sows, gilts):
The presence of a boar at the time of artificial insemination is recommended.
Animals should be checked for signs of oestrus before insemination.
A negative energy balance during lactation may be associated with mobilization of body reserves resulting in a sharp decrease in the thickness of the fat on the back (more than about 30%). In these animals, oestrus and ovulation may be delayed and these animals should be cared for and bred on an individual basis.

Special precautions for safe use in the target species:
Infection may occur if anaerobic bacteria penetrate tissue at the injection site, in particular following intramuscular injection. Use aseptic techniques when injecting the veterinary medicinal product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Buserelin may affect reproductive function, as it has been shown to be foetotoxic in laboratory animals.

Women of childbearing age should handle this veterinary medicinal product with caution. Pregnant women should not administer the veterinary medicinal product.

When administering the veterinary medicinal product, care should be taken to avoid eye and skin contact or accidental self-injection.

In case of accidental eye contact, rinse thoroughly with water. Should skin contact with the veterinary medicinal product occur, wash exposed area immediately with soap and water. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

People with known hypersensitivity to GnRH analogues, benzyl alcohol or any of the excipients should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during all stages of pregnancy in the target animal species.

The veterinary medicinal product is indicated for use in female animals at or close to the time of mating or insemination, and as such use during the luteal phase (after ovulation) is considered safe for use in lactating and non-lactating animals.

Overdose:
None known.

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

7. Adverse events

Cattle (cows), horses (mares), pigs (sows, gilts), rabbits (adult females):

None known.

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

Route of administration:

Cattle, horses and rabbits: intramuscular, intravenous or subcutaneous use.
Pigs: intramuscular or intravenous use.

Dosage:

Cattle (cows): Depending on the indication a single dose of 10 micrograms buserelin per animal (corresponding to 2.5 ml of the veterinary medicinal product) or 20 micrograms buserelin per animal (corresponding to 5.0 ml of the veterinary medicinal product).

Horses (mares): A single dose of 40 micrograms buserelin per animal (corresponding to 10 ml of the veterinary medicinal product).

Pigs (sows, gilts): A single dose of 10 micrograms buserelin per animal (corresponding to 2.5 ml of the veterinary medicinal product).

Rabbits (adult females): A single dose of 0.8 micrograms per animal (corresponding to 0.2 ml of the veterinary medicinal product).

Cattle (cows):
Treatment of infertility associated with follicular cysts:
Administer a single dose of 20 micrograms of buserelin per animal.
A response to treatment is expected within 10-14 days. If a palpable corpus luteum does not develop, or a new cyst forms, the treatment should be repeated. Insemination should be performed at the first oestrus after treatment.

Induction and synchronisation of oestrus and ovulation in combination with F2α (PGF2α) or its analogues, with or without progestogens, as part of a timed artificial insemination protocol:
Judgement on the protocol should be chosen by the responsible veterinarian on the basis of the intended objective and characteristics of the individual herd or animal. The following protocols have been evaluated and could be used:

In cyclic cows:
Day 0: Administer a single dose of 10 micrograms of buserelin per animal.
Day 7: Administer prostaglandin or analogue (at luteolytic dosage).
Day 9: Administer a single dose of 10 micrograms of buserelin per animal.
Artificial insemination 16 to 24 hours after the second buserelin injection of this veterinary medicinal product or at the time of oestrus, if earlier.

In cyclic and non-cyclic cows:
Day 0: Administer a single dose of 10 micrograms of buserelin per animal and insert a progestogen-releasing insert.
Day 7: Remove the progestogen-releasing insert and administer prostaglandin or its analogue (at luteolytic dosage).
Day 9: Administer a single dose of 10 micrograms of buserelin per animal.
Artificial insemination 16 to 24 hours after the second buserelin injection of this veterinary medicinal product or at the time of oestrus, if earlier.

Alternatively:
Day 0: Administer a single dose of 10 micrograms buserelin per animal and insert a progestogen-releasing insert.
Day 7: Remove the progestogen-releasing insert and administer prostaglandin or its analogue (at luteolytic dosage) and PMSG (400 – 500 IU).
Day 9: Administer a single dose of 10 micrograms of buserelin per animal.
Artificial insemination 16 to 24 hours after the second buserelin injection of this veterinary medicinal product or at the time of oestrus, if earlier.

Improvement of conception and / or pregnancy rates in cows with low fertility, during the luteal phase following artificial insemination:
Administer a single dose of 10 micrograms of buserelin per animal 11-13 days after insemination.

Horses (mares):
Induction of ovulation and improvement in conception and / or pregnancy rates:
Administer a single dose of 40 micrograms buserelin per animal on the first day that the follicle reached its optimal size (as determined by previous clinical history and transrectal examinations). Ovulation usually occurs within 24-36 hours after treatment; if the mare has not ovulated during this period, administration should be repeated.

Pigs (sows, gilts):
Induction of ovulation following oestrus synchronisation as part of an insemination program:
Gilts: Administer a single dose of 10 micrograms buserelin per animal, between 115- and 120-hours following oestrus synchronization with a progestogen. A single artificial insemination should be performed 30 - 33 hours after administration of the veterinary medicinal product.
Sows: Administer a single dose of 10 micrograms buserelin per animal, 83 - 89 hours after weaning. A single artificial insemination should be performed 30 - 33 hours after administration of the veterinary medicinal product.

In individual cases, oestrus may not be visible 30 – 33 hours after treatment with the veterinary medicinal product. In such cases, insemination can be carried out later, at a time when oestrus symptoms are present.

Rabbits (adult females):
Induction of ovulation and improvement of conception rate:
Administer a single dose of 0.8 micrograms buserelin per animal, at the time of mating or insemination.
For post-partum insemination administer a single dose of 0.8 micrograms buserelin no less than 24 hours post-partum followed immediately by insemination.

9. Advice on correct administration

The vial can only be broached a maximum of 20 times. When treating groups of animals at the same time, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.

10. Withdrawal periods

Cattle, horses
Meat and offal: Zero days.
Milk: Zero hours.

Pigs, rabbits
Meat and offal: Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 ºC.
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 label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 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

Pack sizes:
Cardboard box containing 1 vial of 10 ml
Cardboard box containing 1 vial of 20 ml
Cardboard box containing 5 vials of 10 ml
Cardboard box containing 1 vial of 100 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>:

Manufacturer responsible for batch release:
Laboratorios Calier S.A.
C/ Barcelonès 26
Polígono Industrial El Ramassà
08520Les Franqueses del Vallès
Barcelona, Spain

Local representative 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.>