

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buserelin aniMedica 0,004 mg/ml – solution for injection for cattle, horses, rabbits (AT, DE, PL)
Busol – 0.004 mg/ml solution for injection for cattle, horses, rabbits (FR, UK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Buserelin acetate	0.0042 mg
(equivalent to Buserelin	0.004 mg)

Excipients:

Qualitative composition of excipients and other constituent	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol	20.0 mg
Sodium chloride	
Sodium dihydrogenphosphate 2H ₂ O	
Sodium hydroxide	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, rabbits

3.2 Indications for use for each target species

In cattle:

- Early cycle induction post partum
- Treatment of follicular cysts
- Improvement of conception rate in artificial insemination procedures, also after synchronisation of oestrus with a PGF2 α analogue. Results may however vary depending on breeding conditions.

In horses:

- Induction of ovulation to synchronise ovulation more closely with mating
- Improvement of conception rate

In rabbits:

- Improvement of conception rate
- Induction of ovulation in post partum insemination.

3.3 Contraindications

None.

3.4 Special warnings

Treatment with a Gonadotropin releasing hormone (GnRH) analogue is only symptomatic; the causes underlying a fertility disorder are not eliminated by this treatment.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Observe aseptic precautions.

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

Avoid eye and skin contact with the solution for injection. In case of accidental eye contact, rinse thoroughly with water. Should skin contact with the veterinary medicinal product occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin. Pregnant women should not administer the veterinary medicinal product, as buserelin has been shown to be foetotoxic in laboratory animals. When administering the veterinary medicinal product, care should be taken to avoid accidental self-injection by ensuring that animals are suitably restrained and the application needle is shielded until the moment of injection. Women of child-bearing age should administer the veterinary medicinal product with caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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

The veterinary medicinal product is intended for use to improve pregnancy rate, induce ovulation etc. and should therefore be used prior to mating or insemination and not during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

Intramuscular, intravenous or subcutaneous use.

The dose per animal is 10 to 20 µg buserelin in cows, 20 to 40 µg buserelin in mares and 0.8 µg buserelin in rabbits.

Species / Indication	ml of the veterinary medicinal product	µg Buserelin
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<u>Cattle</u> Fertility disorders of ovarian origin, in particular:		
Follicular cysts with or without symptoms of nymphomania	5 ml	20 µg
Early cycle induction post partum	5 ml	20 µg
Improvement of conception rate in artificial insemination procedures, also after synchronisation of oestrus with a PGF2α analogue. (Results may however vary depending on breeding conditions)	2.5 ml	10 µg
<u>Mares</u>		
Induction of ovulation to synchronise ovulation more closely with mating. (If ovulation has not occurred within 24 hours after treatment, then the injection should be repeated.)	10 ml	40 µg
Improvement of conception rate	10 ml	40 µg
<u>Rabbits</u>		
For improving the conception rate	0.2 ml	0.8 µg
Induction of ovulation in post partum insemination	0.2 ml	0.8 µg

This veterinary medicinal product is preferably given by intramuscular injection. The intravenous or subcutaneous route may also be used. The veterinary medicinal product should be administered once.

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

No data on overdosing are available.

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, rabbits

Meat and offal Zero days

Cattle, horses

Milk Zero hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QH01CA90

4.2 Pharmacodynamics

Buserelin is a peptide hormone and a synthetic hypothalamic releasing hormone analogue for the gonadotropins LH (luteinising hormone) and FSH (follicle stimulating hormone). The mechanism of action of buserelin is identical to that of natural gonadotropin releasing hormone (GnRH): After hypothalamic neurosecretion, buserelin stimulates the release of FSH and LH from the pituitary into the bloodstream. Via the blood circulation, these hormones act on the ovary to result in follicular maturation, ovulation and luteinisation.

4.3 Pharmacokinetics

After intravenous administration, buserelin is degraded very rapidly: Its half-life is 3 to 4.5 minutes in rats and 12 minutes in guinea-pigs. Buserelin accumulates in the liver, kidneys and pituitary; particularly high concentrations are found in the pituitary approximately 60 minutes post-dose. Enzymatic breakdown of buserelin is detectable in the hypothalamus, pituitary, liver and kidneys.

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 25 °C.

5.4 Nature and composition of immediate packaging

Clear glass (type I) vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap.

Pack size:

5 vials of 10 ml in a cardboard box

Multipack sizes:

50 (10x5) vials of 10 ml in a cardboard box

100 (20x5) vials of 10 ml in a cardboard box

250 (50x5) vials of 10 ml in a cardboard box

500 (100x5) vials of 10 ml in a cardboard box

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

aniMedica GmbH

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buserelin aniMedica 0,004 mg/ml – solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Buserelin acetate	0.0042 mg
(equivalent to Buserelin	0.004 mg)

3. PACKAGE SIZE

5 x 10 ml

50 x 10 ml

100 x 10 ml

250 x 10 ml

500 x 10 ml

4. TARGET SPECIES

Cattle, horses and rabbits.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Intramuscular, intravenous or subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle, horses, rabbits

Meat and offal	Zero days
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Cattle, horses

Milk	Zero hours
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8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS
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15. BATCH NUMBER

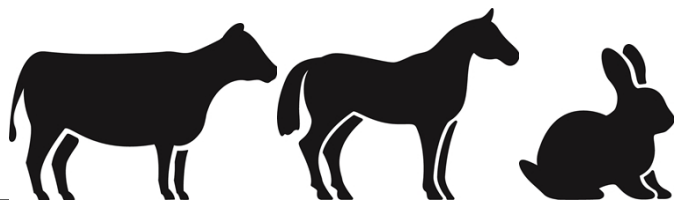
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{LABEL VIAL, 10 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buserelin aniMedica

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

Buserelin acetate	0.0042 mg/ml
(equivalent to Buserelin	0.004 mg/ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days – by: _____.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Buserelin aniMedica 0,004 mg/ml – solution for injection for cattle, horses, rabbits

2. Composition

Each ml contains:

Active substance:

Buserelin acetate	0.0042 mg
(equivalent to Buserelin	0.004 mg)

Excipient(s):

Benzyl alcohol	20.0 mg
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Clear, colourless solution.

3. Target species

Cattle, horses and rabbits.



4. Indications for use

In cattle:

- Early cycle induction post partum.
- Treatment of follicular cysts.
- Improvement of conception rate in artificial insemination procedures, also after synchronisation of oestrus with a PGF2 α analogue. Results may however vary depending on breeding conditions.

In horses:

- Induction of ovulation to synchronise ovulation more closely with mating.
- Improvement of conception rate.

In rabbits:

- Improvement of conception rate.
- Induction of ovulation in post partum insemination.

5. Contraindications

None.

6. Special warnings

Special warnings:

Treatment with a Gonadotropin releasing hormone (GnRH) analogue is only symptomatic; the causes underlying a fertility disorder are not eliminated by this treatment.

Special precautions for safe use in the target species:

Observe aseptic precautions.

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

Avoid eye and skin contact with the solution for injection. In case of accidental eye contact, rinse thoroughly with water. Should skin contact with the veterinary medicinal product occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin. The veterinary medicinal product should not be administered by pregnant women as buserelin has been shown to be foetotoxic in laboratory animals. When administering the veterinary medicinal product, care should be taken to avoid accidental self-injection by ensuring that animals are suitably restrained and the application needle is shielded until the moment of injection. Women of child-bearing age should administer the veterinary medicinal product with caution. 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 product is intended for use to improve pregnancy rate, induce ovulation etc. and should therefore be used prior to mating or insemination and not during pregnancy.

Major incompatibilities:

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

7. Adverse events

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

Intramuscular, intravenous or subcutaneous use.

The dose per animal is 10 to 20 µg buserelin in cows, 20 to 40 µg buserelin in mares and 0.8 µg buserelin in rabbits.

Species / Indication	ml of the veterinary medicinal product	µg Buserelin
<u>Cattle</u> Fertility disorders of ovarian origin, in particular:		
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<u>Mares</u>		
Induction of ovulation to synchronise ovulation more closely with mating. (If ovulation has not occurred within 24 hours after treatment, then the injection should be repeated.)	10 ml	40 µg
Improvement of conception rate	10 ml	40 µg
<u>Rabbits</u>		
For improving the conception rate	0.2 ml	0.8 µg
Induction of ovulation in post partum insemination	0.2 ml	0.8 µg

9. Advice on correct administration

This veterinary medicinal product is preferably given by intramuscular injection. The intravenous or subcutaneous route may also be used. The product should be administered once.

10. Withdrawal periods

Cattle, horses, rabbits

Meat and offal Zero days

Cattle, horses

Milk Zero hours

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

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

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

XXXX

5 x 10 ml

50 x 10 ml

100 x 10 ml

250 x 10 ml

500 x 10 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany
Tel: +49-25363302-0

Local representatives and contact details to report suspected adverse reactions: