1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buserelin aniMedica 0,004 mg/ml – Injektionslösung für Rinder, Pferde, Kaninchen (Germany)
Buserelin aniMedica 0.004 mg/ml – Injektionslösung für Rinder, Pferde, Kaninchen (Austria)
Buserelin aniMedica 0,004 mg/ml roztwór do wstrzykiwań dla bydła, koni i królików (Poland)
Busol – 0.004 mg/ml solution injectable pour bovines, equines, lapins (France)
Busol – 0.004 mg/ml solution for injection for cattle, horses, rabbits (United Kingdom)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution for injection contains:

Active substance:

Buserelin acetate	0.0042 mg
(equivalent to Buserelin	0.004 mg)

Excipient(s):

Benzyl alcohol	20.0 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horse, rabbit

4.2 Indications for use specifying the 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 PGF2α 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals
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 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 product, as buserelin has been shown to be foetotoxic in laboratory animals. When administering the 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 product with caution. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
None known.

4.7 Use during pregnancy, lactation or lay
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.

4.8 Interaction with other medicinal products and other forms of interaction
No data available.

4.9 Amounts to be administered and administration route
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 Buserelin aniMedica	µg Buserelin
Cattle 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
Mares		
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
Rabbits		
Improvement of conception rate	0.2 ml	0.8 µg

Induction of ovulation in post partum insemination	0.2 ml	0.8 µg

Buserelin aniMedica 0.004 mg/ml solution for injection, is preferably given by intramuscular injection. The intravenous or subcutaneous route may also be used. The product should be administered once.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
No data on overdosing are available.

4.11 Withdrawal period(s)
Cattle, horse, rabbit
Meat and offal Zero days

Cattle, horse
Milk Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotropin-releasing hormone,
ATCvet code: QH01CA90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzyl alcohol
Sodium chloride
Sodium dihydrogenphosphate $2H_2O$
Sodium hydroxide
Water for injections

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

6.3 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
Discard unused material.

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 °C)
Do not freeze.

6.5 Nature and composition of immediate packaging

Pack of 5 injection vials (glass type I) each containing 10 ml solution for injection in a carton
Pack of 50 (10x5) injection vials (multipack)
Pack of 100 (20x5) injection vials (multipack)
Pack of 250 (50x5) injection vials (multipack)
Pack of 500 (100x5) injection vials (multipack)

Injection vials with a bromobutyl rubber stopper and an aluminium crimp cap.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 24745/4000

9. RENEWAL OF THE AUTHORISATION

18 January 2010

10 DATE OF REVISION OF THE TEXT

29 March 2010

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.