PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Busol – 0.004 mg/ml solution for injection for cattle, horses, rabbits
Buserelin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Buserelin acetate	0.0042 mg
(equivalent to Buserelin	0.004 mg)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

5 x 10 ml
50 x 10 ml
100 x 10 ml
250 x 10 ml
500 x 10 ml

5. TARGET SPECIES

Cattle, horse and rabbit.

6. INDICATIONS

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.

7. METHOD AND ROUTES OF ADMINISTRATION

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		
For improving the 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.

8. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle, horse, rabbit
Meat and offal Zero days

Cattle, horse
Milk Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by
Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 24745/4000

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Busol – 0.004 mg/ml solution for injection for cattle, horses, rabbits
Buserelin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular injection (intravenous or subcutaneous injection may also be used).

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle, horse, rabbit
Meat and offal Zero days

Cattle, horse
Milk Zero hours

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

EXP {month/year}
Once opened, use by
Shelf life after first opening the immediate packaging: 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

Busol – 0.004 mg/ml solution for injection for cattle, horses, rabbits

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Busol – 0.004 mg/ml solution for injection for cattle, horses, rabbits
Buserelin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Buserelin acetate	0.0042 mg
(equivalent to Buserelin	0.004 mg)

Excipient(s):

Benzyl alcohol	20.0 mg

Clear, colourless liquid.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, horse and rabbit.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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:**		
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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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Cattle, horse, rabbit
Meat and offal Zero days

Cattle, horse
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 after the expiry date which is stated on the label.
Shelf life after first opening the container: 28 days

When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded, should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

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

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.
The product should not be administered by pregnant women 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.

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.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Medicines should not be disposed of via 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.

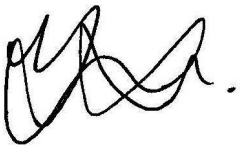
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.



Approved: 08 June 2022