ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal 4 microgram/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

1 vial of 2.5 ml
5 vials of 2.5 ml
10 vials of 2.5 ml
1 vial of 5 ml
5 vials of 5 ml
10 vials of 5 ml
1 vial of 10 ml
5 vials of 10 ml
10 vials of 10 ml
1 vial of 50 ml
5 vials of 50 ml
10 vials of 50 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle, horses, pigs, rabbits: intramuscular, intravenous or subcutaneous use.
Trout: Intramuscular use.

7. WITHDRAWAL PERIODS

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

Pigs, rabbits
Meat and offal: Zero days.

Trout
Meat and offal: Zero degree 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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5065

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Buserelin 4 mcg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Receptal 4 microgram/ml solution for injection

2. Composition

Each ml contains:
Active substance:

Buserelin acetate)	4 microgram (equivalent to 4.2 microgram buserelin

Excipients:

Benzyl alcohol	20 mg

Clear, colourless solution.

3. Target species

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

4. Indications for use

Cattle (heifers, 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 (gilts, sows):

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

Rabbits (adult females):

- Induction of ovulation and improvement in conception rates.

Trout:

- Facilitation of strip spawning.
- Reduction of mortality after stripping.

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, as buserelin, does not eliminate the underlaying 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, heifers):
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 with 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 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 or benzyl alcohol 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, heifers), horses (mares), pigs (sows and gilts), rabbits (adult females), trout:

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:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

Route of administration:

Cattle, horses, pigs, rabbits: intramuscular, intravenous or subcutaneous use.
Trout: intramuscular use, 2cm above the lateral line posterior to the dorsal fin.

Dosage:

Cattle (cows, heifers): 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).

Trout: A single dose of 3 – 4 micrograms per kg bodyweight (corresponding to 0.75 – 1.0 ml of the veterinary medicinal product).

Cattle (cows and heifers):
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.

Trout:
Facilitation of strip spawning and reduction of mortality after stripping:
Administer a single dose of 3-4 micrograms buserelin per kg bodyweight to fish in spawning condition. Stripping should be performed 2-3 days after treatment with the veterinary medicinal product.

9. Advice on correct administration

The stopper may be safely punctured up to 12 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.

Trout
Meat and offal: Zero degree days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
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 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.

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

Marketing authorisation number: Vm 06376/5065

Pack sizes:
Carton box containing 1 vial of 2.5 ml
Carton box containing 5 vials of 2.5 ml
Carton box containing 10 vials of 2.5 ml
Carton box containing 1 vial of 5 ml

Carton box containing 5 vials of 5 ml
Carton box containing 10 vials of 5 ml
Carton box containing 1 vial of 10 ml
Carton box containing 5 vials of 10 ml
Carton box containing 10 vials of 10 ml
Carton box containing 1 vial of 50 ml
Carton box containing 5 vials of 50 ml
Carton box containing 10 vials of 50 ml

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1 a
85176 Unterschleissheim
Germany

Local representative:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, United Kingdom

Contact details to report suspected adverse reactions:
UK(GB)
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

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

Gavin Hall
Approved: 26 May 2026