1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal 4 microgram/ml solution for injection

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	20.0 mg
Sodium chloride	
Sodium dihydrogen phosphate monohydrate	
Sodium hydroxide and/or hydrochloric acid	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

Cattle (cows, heifers):

- 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.

Trout:

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

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, 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 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, heifers), horses (mares), pigs (sows, gilts), rabbits (adult females), trout:

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

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.

Dosage:
Cattle (cows, heifers): 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).

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

Protocols for use:

Cattle (cows, heifers)
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 protocoll:
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.

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

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.

Trout
Meat and offal: Zero degree 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: 18 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

2.5 and 5 ml vials: Colourless glass vials (type I), closed with a laminated, halogenated butyl rubber stopper and an aluminium cap.
10 ml vials: Colourless glass vials (type I), closed with a halogenated butyl rubber stopper and an aluminium cap.
50 ml vials: Colourless glass vials (type II), closed with a halogenated butyl rubber stopper and an aluminium cap.

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.

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

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/123/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

15/08/2025

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).