SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance
Buserelin (as acetate) 0.004 mg
(corresponding to 0.0042 mg buserelin acetate)

PHARMACEUTICAL FORM

Solution for I.M. ,I.V or S.C injection.

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, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, rabbits.

3.2 Indications for use for each target species

- For the treatment of infertility of ovarian origin and improvement of pregnancy rate in cows.

- For the synchronisation of oestrus in dairy cows and for reducing the calving to conception
  interval in these cows when used in conjunction with a PGF 2α analogue with luteolytic activity as part of a 10 day fixed time insemination regime.
- To induce ovulation of a mature follicle and thereby to synchronise ovulation more closely with mating in mares.
- For the improvement of conception rate and induction of ovulation in rabbits.

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:
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.

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 buserelin or benzyl alcohol should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pregnancy rate to first insemination after use of the Intercept fixed time insemination programme in cows may be reduced by some 12% in herds with pregnancy rates to first service above 50% and in first parity animals (heifers). Highest pregnancy rates are achieved by servicing cows between 61-70 days after calving.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/

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

In cattle, horses and rabbits, the preferred route of administration is intramuscular injection (i.m.), but it may also be injected intravenously (i.v.) or subcutaneously (s.c.).
Do not pierce the stopper more than 12 times.
When treating large numbers of animals, use a suitable draw-off needle or automatic dosing syringe to avoid excessive puncturing of the closure.

Cattle: For the treatment of cows with fertility disorders of ovarian origin
Follicular cysts - with or without symptoms of nymphomania - 5.0ml.

In the treatment of follicular cysts in cattle, it is unnecessary to manually express the cysts. A corpus luteum will usually be clearly detectable on either the affected or the normal ovary within about 8 days after administration. At the same time luteinisation and disappearance of the cysts may occur. The response to treatment should be checked after 10-14 days. If no corpus luteum is present, or if newly formed cysts are detected, treatment should be repeated.

Artificial insemination or service may take place during the first oestrus after treatment. On average this occurs 20 days after injection.

Acyclia (true anoestrus) - 5.0ml
To determine that the cow is truly acyclic, two rectal examinations should be carried out with an 11 day interval between examinations. Alternatively, two samples of milk should be taken for milk progesterone assay with an 11 day interval between samples.

Oestrus should occur 8-22 days after treatment. If oestrus has not been observed by this stage, a further rectal examination should be carried out. If there are no palpable structures on the ovaries, then treatment should be repeated. If, however, a corpus luteum is palpated, then prostaglandin F2α or one of its analogues should be administered, thus allowing the animal to return to oestrus 2-3 days later.

Delayed ovulation - 2.5ml
This condition may be treated at the time of artificial insemination or service, or up to 6-8 hours beforehand. Ovulation is usually induced within 24 hours of treatment.

Improvement of pregnancy rate of cows - 2.5ml
The product should be injected at the time of or up to 8 hours before hand. This helps to ensure that ovulation occurs at the correct time after insemination.
Improvement of pregnancy rate may also be achieved by a single injection on day 11 or 12 after insemination by helping to prevent luteolysis and consequent embryo mortality.

Note: The induction of ovulation is not possible in the presence of a functional corpus luteum.

Cattle: For the synchronisation of oestrus in dairy cows
The product can be used as part of a 10-day GnRH/prostaglandin/GnRH oestrus synchronisation and insemination regime to increase submission rates and significantly reduce the calving to conception interval.
The use of the product 7 days prior to prostaglandin increases the proportion of cows able to respond to the prostaglandin and co-ordinates a new follicular wave so more cows will ovulate during a shorter time after prostaglandin. A second Receptal treatment after the prostaglandin further tightens synchrony of ovulation in relation to the service time.
The Intervet GnRH/prostaglandin/GnRH regime (Intercept™) for breeding dairy cows at a pre-planned time without the need for specific heat detection is summarised below:

Day 0	Receptal (2.5 ml)
Day 7	Prostaglandin (at luteolytic dose)
Day 9	Receptal (2.5 ml) 54-56 hours post prostaglandin or at AI if sooner
Day 10 AI	72 hours post prostaglandin or at observed heat if sooner.

When using the Intercept fixed time insemination regime, it is recommended that cows showing signs of oestrus after prostaglandin treatment should be inseminated when observed in oestrus rather than completing the synchronisation programme.

Trials have shown that for cows holding to their first service, use of a GnRH/prostaglandin/GnRH regime can improve the calving to conception interval by 11 days when compared to controls. When including all services, the calving to conception interval was shown to be improved by 7 days.

Horses: For the treatment of mares.
To induce ovulation of a mature follicle and thereby to synchronise ovulation more closely with mating - 10ml

The product should be administered on the first day on which the follicle has reached its maximum size, this being determined by previous clinical history and rectal examinations.

The product is best given approximately 6 hours prior to service. This may be achieved by administering in the morning with service in the afternoon of the same day or alternatively, with the injection given in the early afternoon and service in the evening.

The mare should be served again the next morning if she is still in oestrus. If ovulation has not occurred within 24 hours after treatment, then the injection should be repeated.

Rabbits:
Induction of ovulation for post-partum insemination - 0.2ml
Administer 0.2ml subcutaneously, 24 hours after parturition. Insemination should be carried out directly after administration.

Improvement of conception rate - 0.2ml
Inject 0.2ml at the time of insemination or mating.

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

Meat: Zero days.
Milk: cattle – Zero 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.

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

The expiry date of the product is indicated on the packaging materials.
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

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 10 ml
Carton box containing 1 vial 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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicines products should be disposed of as toxic waste, do not dispose of in the sewer.

6. REGISTRATION NUMBER

174-11-36314-00

7. MANUFACTURER

Intervet international GmbH, Underschleisshiem, Germany.

8. MARKETING AUTHORISATION HOLDER:

Intervet Israel Ltd., Hod HaSharon 45240

Revised in November 2025.