Veterinary medicinal product package leaflet

This medicine is dispensed with a veterinarian's prescription only
For use in animals only

1. **Name, form and strength of the veterinary medicine**
   Receptal Veterinary

2. **Active ingredients**
   Each 1 ml of solution contains:
   0.004 mg buserelin (as acetate)
   and
   20 mg benzyl alcohol as preservative.

For a list of the inactive ingredients and allergens in this medicinal product see the section 'Additional information'.

3. **What is this medicine intended for?**
   - 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.

   Therapeutic group: gonadotropin-releasing hormones.

4. **Contraindications**
   None.

5. **Side effects**
   Pregnancy rate to first insemination after use of the Intercept synchronization protocol in cows may be reduced by about 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.

   Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by following the link:
   https://sideeffects.health.gov.il/

6. **Target animals:**
   Cows, mares, rabbits.

7. **Administration route and dosage:**
   In cows, mares, and rabbits, the preferred route of administration is intramuscular injection (i.m.). The product 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 stopper.

Cattle: For the treatment of cows with fertility disorders of ovarian origin
Follicular cysts with or without symptoms of nymphomania – 5.0 ml.
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) – 5.0 ml
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 – 2.5 ml
This condition may be treated at the time of artificial insemination or service, or up to 6-8 hours beforehand. Ovulation usually occurs within 24 hours of treatment

Improvement of pregnancy rate of cows – 2.5 ml
The product should be injected at the time of or up to 8 hours before service. 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, which helps to prevent luteolysis and 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 generate a new follicular wave so more cows will ovulate during a shorter time after prostaglandin. A second Receptal treatment after prostaglandin administration further tightens synchrony of ovulation in relation to service time.

The Intervet GnRH/prostaglandin/GnRH regime (Intercept™) for breeding dairy cows at pre-planned times without the need for heat detection is summarised below:

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

When using the Intercept synchronization protocol, 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 in mares – 10 ml

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 injection 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 – 0.2 ml
Administer 0.2 ml subcutaneously, 24 hours after parturition. Insemination should be carried out directly after administration.

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

8. **How to use this medicinal product:**
   Observe aseptic precautions.

9. **Withdrawal period:**
   Meat: 0 days.
   Milk: 0 days.

10. **Warnings**

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.

Operator warnings:
Because of the potential for effects on reproductive function, women of child-bearing age should handle this product with caution.
Pregnant women should not handle the product.
When administering the product, care should be taken to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.
Avoid eye and skin contact with the product. 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.

Avoid eye and skin contact with the solution for injection. In case of accidental 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 handle 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 handle this product with caution.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after use.

11. Storage instructions:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C. Protect from light. Keep the vial in the carton.
- Following withdrawal of the first dose, use the product within 28 days and no later than the product's expiry date.
- Discard any remaining, unused product.

12. Instructions for the disposal of unused medicinal product or waste materials:

Dispose of any remaining veterinary medicinal product or waste obtained from using a veterinary medicinal product in the same manner as toxic waste; do not discard into the sewage system.

13. Additional information:

- In addition to the active ingredient, this medicine also contains:
  benzyl alcohol, sodium chloride, sodium dihydrogen phosphate monohydrate, sodium hydroxide, hydrochloric acid, water for injection.
- What the medicine looks like and contents of the pack:
  Solution for injection.
  clear, colourless solution with no visible particles.
- Pack size: 10 ml or 50 ml vial. Not all pack sizes may be marketed.
- **Registration holder's name and address:** Intervet Israel Ltd., Industrial Zone Neve Ne'eman, Hod HaSharon 45240.
- **Manufacturer's name and address:** Intervet International GmBH, Unterschleissheim, Germany.
- Reviewed and approved by the Ministry of Health in July 2024.
- Registration number of the medicine in the Ministry of Health's National Drug Registry: 174-11-36314-00