

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal, 0.004 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition 1 ml contains:
<u>Active substance</u> Buserelin acetate (corresponding to 0.004 mg buserelin)	0.0042 mg
<u>Excipient:</u> Benzyl Alcohol	20 mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, rabbits, pigs (gilts) and trout.

4.2 Indications for use, specifying the 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 2 α 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.

To induce ovulation in pigs (gilts) after oestrus synchronisation in order to facilitate a single fixed time artificial insemination program.

For the improvement of conception rate and induction of ovulation in rabbits.

To facilitate stripping and reduce mortality due to egg binding in rainbow trout.

4.3 Contra-indications

None

4.4 Special warning for each target species

Gilts: Administration of gonadotrophins in this fixed time insemination protocol is not recommended. The presence of the boar at the time of artificial insemination is recommended.

4.5 Special precautions for use

i) Special precautions for use in animals

Observe aseptic precautions.

Gilts: Use of the product contrary to the recommended protocol (see section 4.9) may result in the formation of follicular cysts and may detrimentally affect fertility and prolificacy.

ii) Special precautions to be taken by the person administering the medicinal product to the animals

Because of the potential for effects on reproductive function, women of child-bearing age should handle this product with caution. Pregnant women should not administer 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 product. 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 administer 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 administer the product with caution.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.9 Amount(s) to be administered and administration route

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.).
In pigs, the preferred route of administration is intramuscularly (i.m.), but it may also be injected intravenously (i.v.).

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.

Acycilia (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 F_{2α} 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.

Pigs (gilts):

Induction of ovulation after oestrus synchronisation in order to facilitate a single fixed time artificial insemination programme: 10 µg (2.5 ml)/animal.

Fixed time insemination should be carried out as follows:

- Administration of Receptal 115-120 hours after the end of synchronization treatment with

a progestin.

- A single artificial insemination 30-33 hours after Receptal administration.

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.

Rainbow trout:

To facilitate stripping in male and female fish in spawning condition, and to reduce mortality due to egg binding.

Inject at a dose rate of 0.75-1.0ml per kg bodyweight (3-4 micrograms Buserelin/kg bodyweight) by intramuscular injection, 2cm above the lateral line posterior to the dorsal fin. Stripping should be performed 2-3 days after treatment.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No special precautions required.

4.11 Withdrawal periods

Meat: cattle, horses, pigs and rabbit – Zero days.

Milk: cattle – Zero hours.

Not to be used in trout intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotrophin-releasing hormone

ATC Vet code: QH01CA90

5.1 Pharmacodynamic properties

Buserelin is a synthetic analogue of gonadotrophin releasing hormone (GnRH) which controls luteinising hormone (LH) and the follicle stimulating hormone (FSH) concentrations.

As FSH and LH play a key role in the final maturation of the preovulatory follicle, buserelin has the ability to induce and synchronize ovulation, induce turn over of the cystic follicles and improve conception rate.

5.2 Pharmacokinetic particulars

Cattle:

Following buserelin injection, peak concentrations in blood are achieved 1 hour later. Six hours after injection, plasma buserelin concentrations are back to basal levels.

Higher amounts than the recommended clinical doses do not further increase LH and FSH

concentrations.

Pigs:

Following administration of Buserelin, peak LH concentration in blood was observed at 1.7 hours post injection. Data clearly confirmed that absorption is also rapid in pigs.

Buserelin is rapidly eliminated. Following injection, it accumulates in liver, kidneys and pituitary. The quick inactivation of buserelin by enzymatic breakdown (peptidases) takes place in hypothalamus and pituitary as well as in the liver and kidneys. All metabolites are small inactive peptides.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Sodium chloride
Sodium dihydrogen phosphate monohydrate
Sodium hydroxide (pH adjustment)
Hydrochloric acid (pH adjustment)
Water for injections

6.2 Incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
Discard unused material.

6.5 Nature and composition of immediate packaging

Cardboard box containing colourless Type I glass vials of 2.5 ml, 5 ml, 10 ml or colourless Type II glass vials of 50 ml, closed with a laminated bromobutyl rubber stopper (type I) (2.5 ml and 5 ml vials) or a bromobutyl rubber stopper (type I) (10 ml and 50 ml vials) and an aluminium crimp cap.

Pack sizes:

- 10 vials of 2.5 ml
- 10 vials of 5 ml
- 5 vials of 10 ml
- Single vial of 2.5 ml
- Single vial of 5 ml
- Single vial of 10ml

- Single vial of 50ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicines products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4438

9. DATE OF FIRST AUTHORISATION

28 May 1993

10. DATE OF REVISION OF TEXT

April 2021

Approved: 28/04/21

D. Austin