Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal 0.004 mg/ml Solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance	
Buserelin	0.004 mg
Excipients	
Benzyl alcohol (E1519)	20 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, horses, pigs, rabbits and trout.

4.2 Indications for use, specifying the target species

For use in cases of reduced fertility due to ovarian dysfunction and to induce ovulation and improve conception rates.

Cow:

Cystic ovaries with and without symptoms of nymphomania
Anoestrus
Delayed ovulation
Anovulation
Improvement of conception rate after artificial insemination and oestrus synchronisation
Prophylaxis of fertility disorders by early induction of cycle post partum.

Mare:

Anoestrus
Ovulation induction
Fixing time of ovulation and service
Improvement of conception rate
Prolonged or continuous heat

Gilt:

Induction of ovulation after oestrus synchronisation in order to facilitate a single fixed time artificial insemination programme.

Doe:

Ovulation induction at post partum insemination
Improvement of conception rate

Rainbow trout:

Facilitate stripping in rainbow trout in spawning conditions. Reduce mortality due to egg binding.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Gilts:
Injection of Receptal should be done according to the recommended time schedule. Administration of gonadotrophins in this fixed time insemination protocol is not recommended.

4.5 Special precautions for use

Special precaution(s) for use in animals

Use aseptic procedures to inject the product. Infection may occur if anaerobic bacteria penetrate the tissue at the injection site, in particluar following intramuscular injection.

Gilts:
Use of the product contrary to the recommended protocol (see sectioin 4.9) may result in the formation of follicular cysts and may reduce pregnancy rates.
The presence of the boar at the time of artificial insemination is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to 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 pysician.

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.

4.6 Adverse reactions (frequency and seriousness)

Unknown.

4.7 Use during pregnancy, lactation or lay

With the exception of gilts, the product can be administered at any stage of pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.9 Amounts to be administered and administration route

In cattle, horses and rabbits: Intramuscular injection is the preferred route of administration, but the product may also be administered intravenously or subcutaneously.

In pigs and trout: Intramuscular injection.

Do not pierce the stopper more than 12 times.

Cows	
Fertility disorders of ovarian origin	
- Follicular cysts with or without symptoms of nymphomania	5.0ml
- Acyclia (true anoestrus)	5.0ml
- Delayed ovulation	2.5ml
- Improvement of pregnancy rate in cows	2.5ml
Mares	
Anoestrus	5ml (repeated after 24 hours)
To induce ovulation of a mature follicle and thereby to synchronise ovulation more closely with mating in mares	10 ml

Gilts:

10 µg (2.5 ml)

The product should be adminstered between 115 and 120 hours following oestrus synchronisation with a progestagen.

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

Doe:	
- Induction of ovulation for post-partum insemination	0.2ml
- Improvement of conception rate	0.2ml
Rainbow Trout	
- Facilitate stripping in spawning conditions	0.75 - 1.0 ml/kg bw
- To reduce mortality due to egg binding	0.75 - 1.0 ml/kg bw

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

No special precautions required.

4.11 Withdrawal Period(s)

Meat and offal: Zero days
Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Systemic hormonal preparations, buserelin.
ATCvet code: QH01CA90

5.1 Pharmacodynamic properties

Buserelin is a peptide hormone which is chemically analogous to the releasing hormone (RH) of the luteinising hormone (LH) and follicle stimulating hormone (FSH) thus a gonadotrophin releasing hormone (GnRH) analogue.

The mode of action of Receptal corresponds to the physiologic-endocrinological action of the naturally occurring gonadotrophin releasing hormone.

GnRH leaves the hypothalamus via the hypophyseal portal vessels and enters the anterior lobe of the hypophysis. Here it induces the secretion of the two gonadotrophins FSH and LH into the peripheral blood stream. These then act physiologically to cause maturation of ovarian follicles, ovulation and luteinisation in the ovary.

5.2 Pharmacokinetic properties

Buserelin is rapidly eliminated from the plasma after intravenous administration, its initial half-life being 3 - 4.5 minutes in rats and 12 minutes in guinea pigs. It accumulates in liver, kidneys and hypophysis; high concentrations being found in hypophyseal tissue after about 60 minutes. The inactivation of buserelin by enzymatic breakdown (pepidases) can be demonstrated in the hypothalamus and hypophysis and in liver and kidneys.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium chloride
Sodium dihydrogen phosphate monohydrate
Sodium hydroxide
Hydrochloric acid, concentrated
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 25ºC.
Protect from light.

6.5 Nature and composition of immediate packaging

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

Pack sizes:
Cardboard box with 1 vial of 2.5 ml 5 ml 10 ml or 50 ml.
Cardboard box with 5 vials of 2.5 ml 5 ml 10 ml or 50 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/123/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1999

Date of last renewal: 28th August 2009

10 DATE OF REVISION OF THE TEXT

April 2016