PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal 0.004 mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains 0.004 mg Buserelin and 20 mg benzyl alcohol, as anti-microbial preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

6. INDICATION(S)

Indications: For the treatment of infertility of ovarian origin and improvement of pregnancy rate in cows.
For the synchronisation of oestrus in dairy cows (Intercept TM). To induce ovulation of a mature follicle and thereby to synchronise ovulation more closely with mating in mares. To induce ovulation in pigs (gilts) aeroestrus 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 in trout.
Synthetic releasing hormone for the release of both luteinising andfollicle-stimulating hormones

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For dosage, administration, contraindications, disposal advice and warnings: Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods: Meat: cattle, horses, pigs and rabbits- zero days. Milk: Cattle - zero hours. Not to be used in trout intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Keep the container in the outer carton. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Observe aseptic precautions. Once broached, use by:

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4438

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Label/50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal 0.004 mg/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains 0.004 mg Buserelin and 20 mg Benzyl alcohol, as anti-microbial preservative.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Solution for injection.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN: {number}

7. EXPIRY DATE

Exp end of: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Synthetic releasing hormone analogue for the release of both luteinising and follicle-stimulating hormones.
Keep out of the sight and reach of children.
For intramuscular, intravenous or subcutaneous injection. For uses, dosage, administration, disposal advice and warnings: Read package leaflet before use. Do not store above 25°C. Once opened, use within 28 days. Protect from light. Keep the container in the outer carton. To be supplied only on veterinary prescription.
Distributor for Northern Ireland: Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road, Dublin 24
MA Holder: MSD Animal Health UK Ltd., Walton Manor, Walton, Milton Keynes, MK7 7AJ
POM-V
Vm 01708/4438

PACKAGE LEAFLET FOR:

Receptal 0.004 mg/ml Solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA Holder
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer for bath release
Intervet International GmbH, Feldstrasse 1a, 85716 Unterschleissheim, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Receptal, 0.004 mg/ml solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Clear, colourless solution.1 ml solution for injection contains 0.004 mg of Buserelin and 20 ml Benzyl alcohol as anti-microbial preservative.

4. INDICATION(S)

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.
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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.
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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Observe aseptic precautions.
Gilts: Use of the product contrary to the recommended protocol (see section Dosage and Administration above) may result in the formation of follicular cysts and may detrimentally affect fertility and prolificacy.

10. WITHDRAWAL PERIOD(S)

Meat: cattle, horses, pigs and rabbit – zero days
Milk: cattle – zero hours
Not to be used in trout intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Keep the container in the outer carton. When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

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.
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 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 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 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 retrained 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

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 10 ml; Single vial of 50 ml
Not all pack sizes may be marketed.
POM-V
To be supplied only on veterinary prescription.
Vm 01708/4438
For animal treatment only. Keep out of the sight and reach of children.

Approved: 13/05/21