

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OESTRACTON 52.4 micrograms/ml solution for injection for cattle, horses, pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance:

Gonadorelin[6-D-Phe]acetate 52.4 µg
(equivalent to 50 µg Gonadorelin[6-D-Phe])

Excipient:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl-4-hydroxybenzoate (E 218)	1.0 mg
Sodium hydroxide	
Acetic acid, glacial	
Water for injections	

Clear colourless to brownish-yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cows), cattle (heifers), horses (mares), pigs (sows), pigs (gilts)

3.2 Indications for use for each target species

Control and stimulation of reproduction and improvement of conception rates in cattle and pigs.
Treatment of ovarian-related fertility disorders or dysfunctions in cattle and horses.

Cattle:

- Ovulation induction in case of delayed ovulation due to LH-deficiency
- Ovulation synchronization following oestrus synchronisation
- Stimulation of the ovaries during the puerperal period from Day 12 post partum
- Ovarian cysts (due to LH-deficiency).

Horses:

- Acycilia and anoestrus due to LH-deficiency
- Ovulation induction (shortening of oestrus).

Pigs:

- Ovulation synchronization in association with a PMSG for timed insemination as part of a timed insemination-regime

3.3 Contraindications

Do not use in cows with a mature tertiary follicle ready to ovulate.

Do not use during infectious diseases and other relevant health disorders.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

To maximise conception rates of cows to be treated with GnRH-PGF_{2α} based synchronization protocols, the ovarian status should be determined and regular cyclic ovarian activity confirmed. Optimal results will be achieved in healthy normally cycling cows.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Care should be taken when handling the veterinary medicinal product to avoid self-injection. In case of accidental self- injection, seek medical advice immediately and show the package leaflet or the label to the physician.

The effects of accidental exposure in pregnant women or in women with normal reproductive cycles are unknown; therefore it is recommended that pregnant women should not administer the veterinary medicinal product, and that women of child-bearing age should administer the veterinary medicinal product with caution.

Care should be taken to avoid skin and eye contact. In case of skin contact, rinse immediately and thoroughly with water as GnRH analogues can be absorbed through the skin. In case of accidental contact with eyes, rinse thoroughly with plenty of water.

People with known hypersensitivity to GnRH analogues should avoid contact with the veterinary .

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (cow), cattle (heifer), horses (mare), pigs (sow), pigs (gilt):

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Not applicable.

Lactation:

Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

A synergistic effect occurs in case of a combined administration of FSH, especially in case of a disturbed puerperal course. Simultaneous use of human or equine chorionic gonadotropin may lead to ovarian over-stimulation.

3.9 Administration routes and dosage

Intramuscular or subcutaneous use.

For single injection.

The cap may be safely punctured up to 20 times. When treating groups of animals in one run, it is recommended to use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.

Cows and heifers: 1.0 – 2.0 ml intramuscular (corresponding to 50 – 100 µg of Gonadorelin[6-D-Phe] per animal)

- Ovulation induction in case of delayed ovulation due to LH-deficiency	2.0 ml
- Ovulation synchronisation following oestrus synchronisation	1.0 ml
- Stimulation of the ovaries in the puerperal period from Day 12 post partum	1.0 ml
- Ovarian cysts (due to LH-deficiency)	1.0 ml

Mares: 2.0 ml intramuscular (corresponding to 100 µg of Gonadorelin [6-D-Phe] per animal)

Sows and gilts: 0.5 – 1.5 ml intramuscular or subcutaneous (corresponding to 25 – 75 µg of Gonadorelin[6-D-Phe] per animal)

- Ovulation synchronization in association with a PMSG for timed insemination as part of a timed insemination-regime

- adult sows	0.5 – 1.0 ml
- gilts	1.0 – 1.5 ml

Special information

The ovulation synchronization system includes the administration of PMSG and the veterinary medicinal product after the end of oestrus synchronisation (OeS) (e. g. with Altrenogest) in gilts or after the weaning in adult sows and two artificial inseminations (AI) within a period of 40 – 42 hours.

In adult sows the time table depends on the duration of the suckling period.

Adult sows (suckling period ≥ 33 days):

Interval between weaning and PMSG administration:	24 hours
Interval between PMSG and the veterinary medicinal product administration:	56 hours (± 1 hour)
Interval between the veterinary medicinal product and AI1:	24 – 26 hours
Interval between the veterinary medicinal product and AI2:	40 – 42 hours

The preferred dose of the veterinary medicinal product is 50 µg. However, the administration of 25 µg is also sufficient in case of sows with sow parity of more than 3 or during the mating period of September until May.

In case of shorter suckling periods the time interval between PMSG and the veterinary medicinal product should be extended accordingly:

Suckling period of 4 weeks: 72 hours

Suckling period of 3 weeks: 78 – 80 hours

The time between the veterinary medicinal product administration and the both AI's remain unchanged.

Gilts:

Interval between OeS and PMSG administration: 24 hours after termination of OeS

Interval between PMSG and the veterinary medicinal product administration: 78 – 82 hours

Interval between the veterinary medicinal product and AI1: 24- 26 hours

Interval between the veterinary medicinal product and AI2: ≤ 40 hours

The preferred dose of the veterinary medicinal product is 50 µg. However, the dose may be adjusted within the range of 50–75 µg to take into account farm-specific aspects or seasonal influences. The proposed time table should be strictly kept.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not 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

Cattle, horses, pigs

Meat and offal: Zero days.

Cattle, horses

Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QH01CA01

4.2 Pharmacodynamics

The veterinary medicinal product contains Gonadorelin[6-D-Phe]acetate (synonym = D-Phe⁶-LHRH, D-Phe⁶-luteinising hormone-releasing hormone), a synthetic analogue of the natural gonadotropin releasing hormone GnRH. GnRH is synthesized in the hypothalamus and reaches the hypophysis as a function of the sexual cycle. The central physiological effect of GnRH is the release and the biosynthesis of the gonadotropins LH (luteinizing hormone) and FSH (follicle stimulating hormone) by the gonadotropic cells of the adenohypophysis.

Along with FSH, LH stimulates the release of estrogens from maturing follicles in the ovaries and induces ovulation in the female organism.

Gonadorelin[6-D-Phe]acetate has the same effect as endogenous GnRH: the LH peak in the spontaneous cycle is imitated and causes follicular maturation and ovulation or stimulates a new follicle maturation wave.

4.3 Pharmacokinetics

Substitution of glycine in position 6 of the natural GnRH-decapeptide by D-phenylalanine increases the stability of the molecule towards degradation by specific peptidases, and its endocrinological effects are prolonged.

GnRH and its analogues are rapidly absorbed after parenteral administration and are distributed and eliminated from the organism following one-compartment-model kinetics. Like other peptides Gonadorelin [6-D-Phe] acetate is rapidly degraded. The compound is bio transformed in various organs mainly by enzymatic cleavage of different peptide bonds of the molecule. The degradation products (oligopeptides) are biologically inactive and are excreted renally.

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

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging:

10 ml vial: 2 weeks

50 ml vial: 4 weeks

The date of the first opening of the container should be noted in the provided space on the label and carton.

5.3 Special precautions for storage

Store in a refrigerator (2°C - 8 °C).

Keep the vials in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry data refers to the last day of that month.

Do not use, if you notice any apparent growth or discolouration.

5.4 Nature and composition of immediate packaging

10 ml and 50 ml colourless type I glass vials closed with chlorobutyl rubber stoppers and aluminium caps.

Package sizes

1 x 10 ml solution for injection in a cardboard box

6 x 10 ml solution for injection in a cardboard box

1 x 50 ml solution for injection in a cardboard box

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.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/003/001

8. DATE OF FIRST AUTHORISATION

08/11/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

25/06/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).