SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains:

Active Substance:	
Gonadorelin[6-D-Phe]acetate (corresponding to 50 µg Gonadorelin[6-D-Phe])	52.4 µg
Excipients:	
Methyl-4-hydroxybenzoate (E 218)	1.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear colourless to brownish-yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the 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:
- Acyclia 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

4.3 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 case of known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

To maximise conception rates of cows to be treated with GnRH-$PGF_{2\alpha}$ 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

4.5 Special precautions for use

Special precautions for use in animals
None

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Care should be taken when handling the 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 product, and that women of child-bearing age should administer the 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 medicinal product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Pregnancy
Not applicable

Lactation
Can be used during lactation.

4.8 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.

4.9 Amounts to be administered and administration route

For single intramuscular or subcutaneous 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 Oestracton 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 Oestracton administration:	56 hours (± 1 hour)
Interval between Oestracton and AI1:	24 – 26 hours
Interval between Oestracton and AI2:	40 – 42 hours

The preferred dose of Oestracton 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 Oestracton should be extended accordingly:

Suckling period of 4 weeks:	72 hours
Suckling period of 3 weeks:	78 – 80 hours

The time between the Oestracton 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 Oestracton administration:	78 – 82 hours
Interval between Oestracton and AI1:	24- 26 hours
Interval between Oestracton and AI2:	≤ 40 hours

The preferred dose of Oestracton 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.

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

Not known.

4.11 Withdrawal periods

Cattle, horse, pig	meat and offal:	Zero days
Cattle, horse	milk:	Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:	Systemic hormonal preparations, excl. sex hormone and insulin
ATCvet-code:	QH01CA01 (Gonadorelin)

5.1 Pharmacodynamic Properties

Oestracton contains Gonadorelin[6-D-Phe]acetate (synonym = D-Phe^6-LHRH, D-Phe^6-luteinising hormone-releasing hormone), a synthetic analogue of the natural gonadotropin releasing hormone GnRH. GnRH is synthetized 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.

5.2 Pharmacokinetic Particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl-4-hydroxybenzoate (E218)
Sodium hydroxide
Acetic acid, glacial
Water for injections

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 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

6.4 Special precautions for storage

Store in a refrigerator (2 - 8 °C). Keep the vials in the outer carton.

6.5 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, 6 x 10 ml or 1 x 50 ml solution for injection, packed in an outer cardboard box.

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

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4150

9. DATE OF FIRST AUTHORISATION

4 November 2013

10. DATE OF REVISION OF THE TEXT

March 2019

Approved 21 March 2019