PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Box 1 x 10 ml
Box 6 x 10 ml
Box 1 x 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OESTRACTON 52.4 micrograms/ml solution for injection for cattle, horses, pigs
Gonadorelin[6-D-Phe]acetate

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

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

3. PHARMACEUTICAL FORM

Solution for injection
Clear colourless to brownish-yellow solution

4. PACKAGE SIZE

1 x 10 ml
6 x 10 ml
1 x 50 ml

5. TARGET SPECIES

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

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.m. or s.c. use

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNING(S) IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP:

For 10 ml:
Once a vial has been broached the product must be used within 2 weeks

50 ml:
Once a vial has been broached the product must be used within 4 weeks.

11. SPECIAL STORAGE CONDITIONS

Store at 2 - 8 °C. Keep container in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS; IF ANY

(Any unused product or waste material should be disposed of in accordance with national requirements.)

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. - to be supplied only on veterinarian prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADRESS OF THE MARKETING AUTHORIZATION HOLDER

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

16. MARKETING AUTHORIZATION NUMBER

Vm 08007/4150

17. MANUFACTURER'S BATCH NUMBER

Batch-no.:

10 ml

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OESTRACTON 52.4 micrograms/ml solution for injection for cattle, horses, pigs
Gonadorelin[6-D-Phe]acetate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:

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

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

For i.m. or s.c. use

5. WITHDRAWAL PERIOD

Withdrawal period:

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

6. BATCH NUMBER

Batch-no.:

7. EXPIRY DATE

EXP
Once broached, use by ……

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

50 ml

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OESTRACTON 52.4 micrograms/ml solution for injection for cattle, horses, pigs
Gonadorelin[6-D-Phe]acetate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)

1 ml contains:

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

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

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

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.m. or s.c. use

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNING(S) IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Once broached, use by ……

11. SPECIAL STORAGE CONDITIONS

Store at 2 - 8 °C. Keep container in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS; IF ANY

(Any unused product or waste material should be disposed of in accordance with national requirements.)

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADRESS OF THE MARKETING AUTHORIZATION HOLDER

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

16. MARKETING AUTHORIZATION NUMBER

Vm 08007/4150

17. MANUFACTURER'S BATCH NUMBER

Batch-no.:

PACKAGE LEAFLET

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

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

Marketing authorization holder
Vetoquinol S.A, Magny-Vernois, 70200 Lure, France

Manufacturer responsible for batch release
Wirtschaftsgenossenschaft deutscher Tierärzte (WdT)eG – Siemensstr. 14 – D-30827 Garbsen

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OESTRACTON 52.4micrograms/ml solution for injection for cattle, horses, pigs
Gonadorelin[6-D-Phe]acetate

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

1 ml contains:

Gonadorelin [6-D-Phe]acetate (corresponds with 50 µg Gonadorelin [6-D-Phe])	52.4 µg
Methyl-4-hydroxybenzoate (E 218)	1.0 mg

Pharmaceutical form
Solution for injection - Clear colourless to brownish-yellow solution.

4. INDICATIONS

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 synchronization
- 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

5. 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.

6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

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

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

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 synchronization following oestrus synchronization 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 synchronization (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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 - 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.

Shelf-life after first opening the container
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.

12. SPECIAL WARNING(S)

Special warnings for each target species
To maximise conception rates of cows to be treated with GnRH-PGF2α 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

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.

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.

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

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

.....

15. OTHER INFORMATION

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

Mode of action
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 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.

Following from the potential of GnRH and its analogues like Gonadorelin[6-D-Phe]acetate to stimulate the LH release, these products can be used to regulate ovulation and fertility.

Packaging 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.

Approved 21 March 2019