Gonavet Veyx®

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Solution for injection for cattle, pigs and horses

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Veyx-Pharma GmbH
Soehreweg 6
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Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT
Gonavet Veyx® 50 µg/ml
Solution for injection for cattle, pigs and horses
Gonadorelin[6-D-Phe]

STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS
Active substance:
Gonadorelin[6-D-Phe] 50.0 µg/ml
(equivalent to 52.4 µg/ml Gonadorelin[6-D-Phe]acetate)

Excipients:
Chlorocresol 1.0 mg/ml

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

Cattle (cows, heifers):
- Ovulation induction in case of delayed ovulation due to LH deficiency
- Induction/synchronisation within the framework of systems for timed inseminations
- Stimulation of the ovaries during the puerperal period from day 12 post partum
- Ovarian cysts (due to LH deficiency)

Pigs (sows, gilts):
- Induction/synchronisation of ovulation within the framework or systems for timed insemination and parturition synchronisation

Horses (mares):
- Acyclia and anoestrus due to LH-deficiency

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.

ADVERSE REACTIONS
None known.

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

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
For intramuscular or subcutaneous injection. For intramuscular use, preferably in the neck region. The product is intended for single administration except when used as part of the “Ovsynch” timed artificial insemination protocol. Dosage in ml product and micrograms Gonadorelin[6-D-Phe] per animal.

Cattle (cows and heifers):

by intramuscular injection: (corresponding to 50 - 100 µg of Gonadorelin[6-D-Phe])	1.0 - 2.0 ml
- Ovulation induction in case of delayed ovulation due to LH-deficiency	2.0 ml
- Inductions/synchronisation of ovulation within the framework of systems for timed inseminations	1.0 - 2.0 ml
- Stimulation of the ovaries during the puerperal period from day 12 post partum	1.0 ml
- Ovarian cysts (due to LH-deficiency)	2.0 ml

Pigs (sows and gilts):

by intramuscular or subcutaneous injection: (corresponding to 25 - 75 µg of Gonadorelin[6-D-Phe])	0.5 - 1.5 ml
- Induction/synchronisation of ovulation within the framework of systems for timed inseminations and parturition synchronisation	
Sows:	0.5 - 1.0 ml
Gilts:	1.0 - 1.5 ml

Horses (mares):

by intramuscular injection: (corresponding to 100 µg of Gonadorelin[6-D-Phe])	2.0 ml

The rubber stopper of the vial may be safely punctured up to 25 times. Otherwise, automatic syringe equipment, or a suitable draw-off needle, should be used for the 20 ml and 50 ml vials to avoid excessive puncturing of the closure.

Special information

Cattle:

For oestrus and ovulation synchronisation and timed artificial insemination (AI) in cattle the so called "Ovsynch-procedure" was developed, which consists of the combined use of GnRH and $PGF^{2\alpha}$. The following timed AI protocol has been commonly reported in the literature:

Day 0:	Inject 100 µg of Gonadorelin[6-D-Phe] per animal (2 ml of the product)
Day 7:	Inject $PGF_{2\alpha}$ or analogue (luteolytic dose)
Day 9:	Inject 100 µg of Gonadorelin[6-D-Phe] per animal (2 ml of the product)
AI:	16 - 20 hours later, or at observed oestrus if sooner

The Ovsynch-procedure may not be as efficacious in heifers as in cows.

Pigs:

The ovulation synchronisation system includes the administration of Peforelin or PMSG after the end of oestrus synchronisation with Altrenogest in gilts or after the weaning in adult sows and two timed artificial inseminations. In adult sows the time table depends on the duration of the suckling period. The following procedures are recommended:

	Gilts[1]	Adults sows[2]
Induction of oestrus	**Peforelin** 48 h or **PMSG (eCG)** 24 h - 48 h after last application of Altrenogest	**Peforelin** or **PMSG** application 24 h after weaning
Synchronisation of ovulation	**Gonadorelin[6-D-Phe]** 78 - 80 h after Peforelin or PMSG application	*Suckling period > 4 weeks:* **Gonadorelin[6-D-Phe]** 56 - 58 h after Peforelin or PMSG application *Suckling period 4 weeks:* **Gonadorelin[6-D-Phe]** 72 h after Peforelin or PMSG application *Suckling period 3 weeks:* **Gonadorelin[6-D-Phe]** 78 - 80 h after Peforelin or PMSG application
1st AI	24 - 26 h after **Gonadorelin[6-D-Phe]** application	24 - 26 h after **Gonadorelin[6-D-Phe]** application
2nd AI	40 - 42 h after **Gonadorelin[6-D-Phe]** application	40 - 42 h after **Gonadorelin[6-D-Phe]** application

[1] *The preferred dose of Gonavet Veyx in gilts is 50 µg Gonadorelin[6-D-Phe]. 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.*

[2] *The preferred dose of Gonavet Veyx in adult sows is 50 µg Gonadorelin[6-D-Phe]. 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. The proposed time table should be strictly kept.*

ADVICE ON CORRECT ADMINISTRATION

None.

WITHDRAWAL PERIODS

Cattle, horses, pigs:	Meat and offal	Zero days
Cattle, horses:	Milk	Zero hours

SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C - 8 °C). Keep the vial in the outer carton in order to protect from light.
Do not store above 25 °C after opening.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after „EXP". The expiry date refers to the last day of that month. Shelf life after first opening the immediate packaging: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided on the label.

SPECIAL WARNING(S)

Special warnings for each target species:
To maximise conception rates of cows to be treated with GnRH-$PGF_{2\alpha}$ based synchronisation 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 for use:
Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Administration should be performed with caution in order to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. As GnRH analogues can be absorbed through the skin, accidental spillage onto skin or into the eyes should be thoroughly rinsed off with water. The veterinary medicinal product should not be administered by pregnant women. Women of child-bearing potential should administer the product with caution. People with known hypersensitivity to GnRH should not use this veterinary medicinal product.

Use during pregnancy, lactation or lay:

Pregnancy:
Not applicable.

Lactation:
Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:
A synergistic effect occurs in case of combined administration with FSH. Simultaneous use of human or equine chorionic gonadotropin may lead to ovarian overstimulation.

Overdoses (symptoms, emergency procedures, antidotes, if necessary:
None known.

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

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.

To be supplied only on veterinary prescription.

OTHER INFORMATION

Package sizes:
10 ml vial
20 ml vial
50 ml vial

Not all package sizes may be marketed.