1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gonavet Veyx 50 µg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Federelin 50.0 µg
(equivalent to 52.4 µg Federelin acetate)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	1.0 mg
Sodium hydroxide (for pH adjustment)	
Acetic acid, glacial (for pH adjustment)	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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/synchronization of ovulation 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/synchronization of ovulation within the framework of systems for timed insemination and parturition synchronization

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

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-$PGF_{2\alpha}$ 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.

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:
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 avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

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

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 combined administration with 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 use, preferably in the neck region. Subcutaneous use.

The veterinary medicinal product is intended for single administration except when used as part of the "Ovsynch" timed artificial insemination protocol. Dosage in ml of the veterinary medicinal product and µg Federelin per animal.

Cattle (cows and heifers) by intramuscular injection: 1.0 - 2.0 ml
(corresponding to 50 – 100 µg of Federelin)
- Ovulation induction in case of delayed ovulation due to LH-deficiency 2.0 ml
- Induction/synchronization 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: 0.5 - 1.5 ml
(corresponding to 25 – 75 µg of Federelin)
- Induction/synchronization of ovulation within the framework of systems for timed inseminations and parturition synchronization
  Sows: 0.5 - 1.0 ml
  Gilts: 1.0 - 1.5 ml

Horses (mares) by intramuscular injection: 2.0 ml
(corresponding to 100 µg of Federelin)

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 synchronization 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 Federelin per animal (2 ml of the product)
Day 7:	Inject $PGF_{2\alpha}$ or analogue (luteolytic dose)
Day 9:	Inject 100 µg of Federelin 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 synchronization 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*	Adult sows**
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
Synchronization of ovulation	**Federelin** 78 - 80 h after Peforelin or PMSG application	*Suckling period > 4 weeks:*

		Federelin 56 - 58 h after Peforelin or PMSG application *Suckling period 4 weeks:* **Federelin** 72 h after Peforelin or PMSG application *Suckling period 3 weeks:* **Federelin** 78 - 80 h after Peforelin or PMSG application
1st AI	24 - 26 h after Federelin application	24 - 26 h after Federelin application
2nd AI	40 - 42 h after Federelin application	40 - 42 h after Federelin application

* The preferred dose of the veterinary medicinal product in gilts is 50 µg Federelin. 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.
** The preferred dose of veterinary medicinal product in adult sows is 50 µg Federelin. 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.

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

None 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, pigs, horses:
Meat and offal: Zero days.

Cattle, horses:
Milk: Zero hours.

4. PHARMACOLOGICAL IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QH01CA01

4.2 Pharmacodynamics

Federelin is an agonist of the natural gonadotropin releasing hormone (GnRH) formed in the hypothalamus that is excreted in a pulsatile manner into the pituitary portal vein circulation and controls the synthesis of the follicle stimulating hormone (FSH) and luteinising hormone (LH) in the gonadotropic cells of the anterior pituitary gland as well as LH secretion. The pulse frequency and amplitude of the GnRH excretion are dependent on the stage of the cycle. Along with FSH, LH stimulates the release of estrogens from maturing follicles in the ovaries and induces ovulation in the female organism.
Federelin 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.
With high dosage repeated or continuous application of an agonist, the gonadotropic cells in the pituitary become temporarily refractory.

4.3 Pharmacokinetics

Following parenteral administration, GnRH and its analogues are absorbed rapidly and are distributed and eliminated from the organism following one-compartment-model kinetics. The plasma half-life is a few minutes (natural GnRH) up to 2 hours. The biological half-life of the natural, as well as the synthetic agonists, is short. Break-down occurs by enzymes in the form of peptidases and the excretion is primarily renal. The degradation products have no hormonal activity.

Federelin is a linear decapeptide that can only be differentiated using the difference in the amino acid at position 6 of GnRH: instead of glycine in GnRH the agonist contains D-phenylalanine. This modification leads to a higher resistance against the catabolising enzymes.

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: 28 days.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

Vial of colourless glass, type I, with a fluorinated bromobutyl stopper and an aluminium cap.

1 vial (10 ml) in a cardboard box.
1 vial (20 ml) in a cardboard box.
1 vial (50 ml) 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

Veyx-Pharma GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

20/03/2015

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

11/05/2026

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).