1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folltropin 700 IU Powder and Solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial of lyophilized product contains:
Active substance:
Follicle Stimulating Hormone (FSH) 700 IU

One vial of solvent contains:
Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	360 mg

One ml of reconstituted solution contains:
Active substance:
Follicle Stimulating Hormone (FSH) 35 IU

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	18 mg
Water for Injections	
Sodium Chloride	
Sodium hydroxide	
Hydrochloric acid	

Powder: Freeze dried off-white to slightly pink powdered cake
Solvent: Clear, colourless solution
Reconstituted solution: Clear, slightly pink solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (reproductively mature females).

3.2 Indications for use for each target species

To induce superovulation in reproductively mature heifers or cows.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in males and reproductively immature female cattle.
Do not use in pregnant cattle.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The product should only be used in clinically healthy cows and mature heifers, which are cycling normally. There is a wide range in response to superovulation between animals. There may be a small proportion of non-responders in any group treated.

Collection of embryo is normally started on day 7 following observed oestrus or first breeding. Prior to breeding and the collection of fertilized embryo from these animals, oestrus will have to be induced with prostaglandin F2α or a prostaglandin F2α analogue.

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. Accidental self-injection of FSH may cause biological effects in women and to the unborn child. In case of accidental self- injection in women who are pregnant, or whose pregnancy status is unknown, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: cattle (reproductively mature females).

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Ovarian cyst*, lack of heat**

* Following administration for three superovulation cycles, but did not prevent pregnancy.

** Following superovulation a delayed return to heat is possible.

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:

Laboratory studies with FSH in rats and rabbits have shown evidence of embryotoxicity/foetotoxicity. The safety of the veterinary medicinal product has not been established during pregnancy. Do not use in pregnant cattle.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For intramuscular administration only.

Dissolve each vial of freeze-dried product with the enclosed solvent. Reconstitution and subsequent withdrawal of product should be performed using strict aseptic technique.

Regimen:

Start injections on day 8 to 10 following observed or induced oestrus. Administer 2.5 ml (87 .5 I.U.) of the product intramuscularly, twice daily, for 4 days. In conjunction with the 6th dose of the product, administer prostaglandin F2α or a prostaglandin F2α analogue, at their manufacturer's recommended dose, to cause luteolysis.

Inseminate animals at 12 and 24 hours after the onset of oestrus or 60 and 72 hours after prostaglandin treatment. Additional inseminations may be conducted at 12 hour intervals if indicated.

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

Cows were able to respond to the product consistently throughout a series of 3 treatments. No adverse reactions were detected in treated cows after the injection of 400 mg of the product as a single dose.

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

Meat and offal: Zero days.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QG03GA90

4.2 Pharmacodynamics

Follicle Stimulating Hormone from an extract of porcine pituitary glands for use in cattle. FSH

is the initiator of ovarian activity since it directly promotes growth of ovarian follicles.
The administration of exogenous FSH to mammals at the time of follicular wave emergence stimulates growth of all follicles over 1.7 mm diameter which would normally be lost to atresia during each oestrus cycle. Multiple growing follicles require FSH stimulation until they are mature enough to respond to LH for the final stages of maturation and ovulation. This usually takes a period of approximately 4 days. In cattle, fertilised ova produced by superovulation with FSH, PMSG and other pharmacological agents containing high concentrations of LH have shown reduced fertilisation. The productcontains porcine pituitary extract with FSH activity and low LH activity.

4.3 Pharmacokinetics

When administered by intramuscular injection, FSH of porcine origin is rapidly absorbed from the site of injection. It has a half-life of 5 hours and FSH cannot be detected in the blood stream 12 hours after injection. FSH is inactivated by the liver and then excreted by the kidneys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: Freeze-dried powder and solvent vials: 4 years.

Shelf-life after reconstitution according to directions: 4 days.

5.3 Special precautions for storage

Freeze dried powder and solvent vials: Do not store above 25ºC.

Reconstituted solution: Store in a refrigerator (2 - 8ºC).

Keep the vials in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box containing one vial of powder and one vial of 20 ml of solvent.

Freeze-dried powder
Clear glass 20 ml vial (Type I), with halobutyl rubber stopper (Type I) and red flip-off cap.

Solvent
Clear glass 20 ml vial (Type I), with halobutyl rubber stopper (Type I) and yellow flip-off cap.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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)

VPA10521/043/001

8. DATE OF FIRST AUTHORISATION

06/11/2015

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

11/09/2026

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*).