Summary of Product Characteristics

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:

Excipients

Benzyl alcohol (E1519)	360	mg

One ml of reconstituted solution contains:

Active substance:

Follicle Stimulating Hormone (FSH)	35	IU

Excipients

Benzyl alcohol (E1519)	18	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.
Powder: Freeze dried off-white powder.
Solvent: Clear, colourless solution.
Reconstituted solution: Clear, slightly pink solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (reproductively mature females).

4.2 Indications for use, specifying the target species

To induce superovulation in reproductively mature heifers or cows.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

Following the administration of the product for three superovulation cycles, ovarian cysts occurred in some cows, but these did not prevent pregnancy.
Following superovulation a delayed return to heat is possible.

4.7 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 product has not been assessed in pregnant cattle. Do not use in pregnant cattle.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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.

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

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.

4.11 Withdrawal period(s)

Meat and offal: Zero days
Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, gonadotrophins.
ATCvet code: QG03GA90

5.1 Pharmacodynamic properties

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 product contains porcine pituitary extract with FSH activity and low LH activity.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Freeze dried powder
None
Solvent
Water for Injections
Sodium Chloride
Benzyl Alcohol (E1519)
Sodium hydroxide
Hydrochloric acid

6.2 Major incompatibilities

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

6.3 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.

6.4 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.

6.5 Nature and composition of immediate packaging

Cardboard box containing one vial of powder and one vial of solvent.
<u>Freeze-dried powder</u>
Clear glass 20 ml vial (Type I), with halobutyl rubber stopper (Type I) and red flip-off cap.
<u>Solvent</u>
Clear glass 20 ml vial (Type I), with halobutyl rubber stopper (Type I) and yellow flip-off cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 December 2001
Date of last renewal: 16 June 2017

10 DATE OF REVISION OF THE TEXT

July 2019