ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folltropin 700 IU Powder and Solvent for Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCE

Powder vial: 700 IU FSH

3. PACKAGE SIZE

1 powder vial and 1 solvent vial

4. TARGET SPECIES

Cattle (reproductively mature females).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use only.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted, use within 4 days.

9. SPECIAL STORAGE PRECAUTIONS

Freeze-dried powder and solvent vials: Do not store above 25°C.
Reconstituted solution: store in a refrigerator (2 - 8ºC).
Keep the vials in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 08007/3004

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

CLEAR GLASS 20ML VIAL (FSH)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folltropin

2. STATEMENT OF ACTIVE SUBSTANCES

Each 20ml vial contains FSH equivalent to 700 IU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted, use within 4 days.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

CLEAR GLASS 20ML VIAL (SOLVENT)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folltropin solvent for solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

20ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Folltropin 700 IU Powder and Solvent for Solution for Injection.

2. Composition

Powder vial contains:
Active substance
Follicle Stimulating Hormone (FSH) 700 IU

Solvent vial contains:
Excipients
Benzyl alcohol 360 mg

One ml of reconstituted solution contains:
Active substance:
Follicle Stimulating Hormone (FSH) 35 IU
Excipients
Benzyl alcohol 18 mg

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

3. Target species

Cattle (reproductively mature females).

4. Indications for use

To induce superovulation in reproductively mature heifers or cows.

5. Contraindications

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

6. Special warnings

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.

Pregnancy:
Laboratory studies with FSH in rats and rabbits have shown embryotoxicity/foetotoxicity. The safety of the product has not been assessed in pregnant cattle. Do not use in pregnant cattle.

Overdose:
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.

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

7. Adverse events

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

No adverse reactions were detected in cows after injecting 400 mg as a single dose.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.'

8. Dosage for each species, routes and method of administration

For intramuscular administration only.

Dissolve each vial of freeze-dried product with the enclosed solvent.

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.

Breed 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 hours intervals.

9. Advice on correct administration

Dissolve the product only with the solvent provided. Use strict aseptic technique when preparing and withdrawing the product.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

Freeze-dried powder and solvent vials: Do not store above 25 °C.
Reconstituted solution: store in a refrigerator (2 - 8°C)
Keep the vials in the outer carton in order to protect from light.
Shelf life following reconstitution according to directions: 4 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
When the product is reconstituted, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Do not freeze after mixing. Discard any unused portion of the reconstituted solution.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 08007/3004

Pack Sizes: Cardboard box containing one vial of powder and one vial of 20 ml of solvent.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

Local representatives and contact details to report suspected adverse reactions:
To be completed nationally.

17. Other Information

To be completed nationally.

Gavin Hall

Approved 14 December 2024