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
Follicle Stimulating Hormone (FSH)

2. STATEMENT OF ACTIVE SUBSTANCE

Powder vial: 700 IU FSH

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. PACKAGE SIZE

1 powder vial and 1 solvent vial

5. TARGET SPECIES

Cattle (reproductively mature females).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use only. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

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

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northants
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4145

17. MANUFACTURER'S BATCH NUMBER

LOT:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

CLEAR GLASS 20ML VIAL (FSH)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folltropin 700 IU Powder for solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Follicle Stimulating Hormone for Injection
Each 20ml vial contains FSH equivalent to 700 IU

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

700 IU

4. ROUTE(S) OF ADMINISTRATION

i.m.

5. WITHDRAWAL PERIOD(S)

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

6. BATCH NUMBER

LOT:

7. EXPIRY DATE

EXP: <month/year>
Once reconstituted, use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

i.m.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

LOT:

7. EXPIRY DATE

EXP: <month/year>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Folltropin 700 IU Powder and Solvent for Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northants
NN12 7LS

Manufacturer responsible for batch release:

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Folltropin 700 IU Powder and Solvent for Solution for Injection.
Follicle Stimulating Hormone

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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 powder
Solvent: Clear, colourless solution
Reconstituted solution: Clear, slightly pink solution.

4. INDICATION(S)

For use in reproductively mature heifers or cows to induce superovulation.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

No adverse reactions were detected in cows after injecting 400 mg as a single dose. Following superovulation a delayed return to heat is possible.
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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (reproductively mature females).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 hour 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 PERIOD(S)

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 WARNING(S)

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.

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 (symptoms, emergency procedures, 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.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2017

15. OTHER INFORMATION

Pack Sizes: Cardboard box containing one vial of powder and one vial of solvent.

Approved 28 August 2018