ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prolusyn 50 micrograms/ml solution for injection for cattle
Gonadorelin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 µg of gonadorelin (as gonadorelin acetate)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Cattle: cows, heifers.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
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

10. EXPIRY DATE

EXP {month/year}
Shelf-life after broaching the immediate packaging: 28 days.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Keep vial in outer carton in order to protect from light.
Do not store above 25 °C.

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

Syn Vet-Pharma Ireland Limited
Business Service Group
7A Durands Court
45 Parnell Street
Waterford X91 P381
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 54400/4000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prolusyn 50 µg/ml solution for injection for cattle
Gonadorelin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains 50 µg of gonadorelin (as gonadorelin acetate)

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use.

5. WITHDRAWAL PERIOD(S)

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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first broaching the immediate packaging: 28 days
Once broached, use by:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Prolusyn 50 micrograms/ml solution for injection for cattle

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

Marketing authorisation holder:
Syn Vet-Pharma Ireland Limited
Business Service Group
7A Durands Court
45 Parnell Street
Waterford X91 P381
Ireland

Manufacturer responsible for batch release:
V.M.D. NV
Hoge Mauw 900,
2370, Arendonk,
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prolusyn 50 micrograms/ml solution for injection for cattle
Gonadorelin

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

Each ml contains:

Active substance:

Gonadorelin	(as gonadorelin acetate)	50.0 µg

Excipient:

Benzyl alcohol (E1519)	9.0 mg

Clear, colourless solution.

4. INDICATION(S)

Induction and synchronisation of oestrus and ovulation in combination with prostaglandin F2α (PGF2α) or analogue with or without progesterone as part of Fixed Time Artificial Insemination (FTAI) protocols.
Treatment of delayed ovulation.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use during infectious diseases and other relevant health disorders.

6. ADVERSE REACTIONS

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: cows, heifers.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.
100 µg of gonadorelin (as acetate) per animal in a single injection.
i.e. 2 ml of the product per animal.

Judgement on the protocol to be used should be made by the veterinarian responsible for treatment, on the basis of the treatment objectives of the individual herd or cow. The following protocols have been evaluated and could be used:

Induction and synchronisation of oestrus and ovulation in combination with a prostaglandin F2α (PGF2α) or analogue:
• Day 0: First injection of gonadorelin (2 ml of the product)
• Day 7: Injection of prostaglandin (PGF2α) or analogue
• Day 9: Second injection of gonadorelin (2 ml of the product) should be done.

The animal should be inseminated within 16-20 hours after the last injection of the product or at observed oestrus if sooner.

Induction and synchronisation of oestrus and ovulation in combination with a prostaglandin F2α (PGF2α) or analogue and a progesterone releasing intravaginal device:
The following FTAI protocols have been commonly reported in the literature:
• Insert progesterone releasing intravaginal device for 7 days.
• Inject gonadorelin (2 ml of the product) at the progesterone device insertion.
• Inject a prostaglandin (PGF2α) or analogue 24 hours prior to device removal
• FTAI 56 hours after removal of the device, or
• Inject gonadorelin (2 ml of the product) 36 hours after progesterone releasing intravaginal device removal and FTAI 16 to 20 hours later.

Treatment of delayed ovulation:
GnRH is injected during oestrus.
To improve the pregnancy rates, the following timing of injection and insemination should be followed:
- injection should be performed between 4 and 10 hours after oestrus detection
- an interval of at least 2 hours between the injection of GnRH and artificial insemination is recommended
- artificial insemination should be carried out in accordance with the usual field recommendations, i.e., 12 to 24 hours after oestrus detection.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Meat and offal: zero days
Milk: zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep vial in outer carton in order to protect from light.
Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton after “EXP”. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for each target species

The response of dairy cows to synchronisation protocols may be influenced by the physiological state at the time of treatment, which includes age of the cow, body condition, health status and interval from calving.
Responses to treatment are not uniform either across herds or across cows within herds.
Where a period of progesterone treatment is included in the protocol, the percentage of cows displaying oestrus within a given period is usually greater than in untreated cows and the subsequent luteal phase is of normal duration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Gonadorelin is a Gonadotropin Releasing Hormone (GnRH) analogue which stimulates the release of sex hormones. The effects of accidental exposure to GnRH analogues in pregnant women or in women with normal reproductive cycles are unknown; therefore it is recommended that pregnant women should not administer the product, and that women of child-bearing age should administer the product with caution.
Care should be taken when handling the product to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Since GnRH analogues can be absorbed through the skin and benzyl alcohol may cause mild local irritation, care should be taken to avoid skin and eyes contact. In case of skin and/or eye contact, rinse immediately and thoroughly with plenty of water

GnRH analogues and benzyl alcohol may cause hypersensitivity (allergy). People with known hypersensitivity to GnRH analogues or benzyl alcohol should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:

Can be used during lactation.
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic or embryotoxic effects.
Observations in pregnant cows receiving the product in early pregnancy have not shown evidence of negative effects on bovine embryos.
Inadvertent administration to a pregnant animal is unlikely to result in adverse effects.

Interaction with other medicinal products and other forms of interaction:
A synergistic effect is possible when used in combination with FSH. Simultaneous use of human or equine chorionic gonadotropin can lead to ovarian overstimulation.

Overdose (symptoms, emergency procedures, antidotes):
Up to 5 times the recommended dose and in a regimen extended from one to three daily administrations, no measurable signs of either local or general clinical intolerance are observed.

Incompatibilities:
In the absence of compatibility studies this veterinary medicinal product must not be mixed with any other veterinary medicinal products.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist 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

September 2021

15. OTHER INFORMATION

Box containing 1 vial of 20 ml.

Approved: 01/10/21