ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fixplan 200 IU/ml lyophilisate and solvent for solution for injection
Gonadotrophin, equine serum

2. STATEMENT OF ACTIVE SUBSTANCES

Lyophilisate vial: 5000 IU gonadotrophin, equine serum
Solvent vial: 25 ml

After reconstitution, each ml contains 200 IU gonadotrophin, equine serum

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.

4. PACKAGE SIZE

5,000 IU lyophilisate vial and 25 ml of solvent vial

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle
Meat and offal: Zero days
Milk: Zero hours

Sheep
Meat and offal: Zero days
Milk: Zero hours

Pigs
Meat and offal: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C).
Keep the vials in the outer carton in order to protect from light.
The reconstituted solution should be stored in the refrigerator (2°C - 8°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 54400/4001

17. MANUFACTURER'S BATCH NUMBER

Batch> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL (LYOPHILISATE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fixplan 200 IU/ml lyophilisate for solution for injection
Gonadotrophin, equine serum

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each vial contains 5,000 IU of gonadotrophin, equine serum

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

5,000 IU

4. ROUTE(S) OF ADMINISTRATION

IM
Read package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods
Cattle, sheep, pigs
Meat and offal: Zero days.
Cattle, sheep
Milk: Zero hours.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted, use within 24h.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL LABEL (SOLVENT)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Fixplan 200 IU/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

25 ml

4. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. WITHDRAWAL PERIOD(S)

Read package leaflet before use.

4. STORAGE CONDITIONS

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Fixplan 200 IU/ml lyophilisate 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:
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

Fixplan 200 IU/ml lyophilisate and solvent for solution for injection
Gonadotrophin, equine serum

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

Lyophilisate vial contains:
Active substance
Gonadotrophin, equine serum 5000 IU

Solvent vial contains 25 ml

Each ml of the reconstituted solution contains:

Active substance:
Gonadotrophin, equine serum 200 IU

Lyophilisate: white powder
Solvent: clear colourless solution
Reconstituted solution: clear colourless solution free from visible particles.

4. INDICATION(S)

To stimulate the development of the ovarian follicle in the female.
Cows: Treatment of anoestrus/ induction of oestrus, induction of superovulation and increase in fertility rates after progestagen pre-treatment.
Ewes: Increase in fertility rates after progestagen pre-treatment.

Sows: Treatment of anoestrus post-weaning/ induction of oestrus

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In rare cases, as with all protein preparations, anaphylactic reactions may occur shortly after injection (see section 12).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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, sheep and pigs.

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

Routes of administration: Cattle and sheep: intramuscular use; pigs: intramuscular or subcutaneous use.

Female animals	**Indication**	**Dosage and administration**
Cattle	Anoestrus/oestrus induction	500 – 1,000 IU (*i.e.* 2.5 to 5ml of product), IM
	Superovulation	1,500 – 3,000 IU (*i.e.* 7.5 to 15 ml of product), IM, between day 8 – 13 of the cycle, followed by prostaglandin, IM, 48 hours later
	Increase in fertility rate after progestagen pre-treatment	300 – 750 IU (*i.e.* 1.5 to 3.75 ml of product), IM at the end of a progestagen treatment
Sheep	Increase in fertility rate after progestagen pre-treatment (in and out of breeding season)	400 - 750 IU (*i.e.* 2.0 to 3.75 ml of product), IM, at time of progestagen removal
Pig	Anoestrus post-weaning (induction of oestrus is difficult until 40 days post partum)	1000 IU (*i.e.* 5 ml of product), SC, or IM, fertile oestrus usually follows within 3 – 7 days

Anoestrus is often caused by inadequate management (feeding and housing). Improvement of management is therefore a prerequisite for a successful treatment.

Equine serum gonadotropin is a protein hormone which acts on the ovary to stimulate the production of follicles. The number of follicles produced can be influenced by the dose of equine serum gonadotropin administered and this must be taken into account when, for instance, calculating the dose for a particular flock of ewes in which oestrus synchronisation is desired. In general, the further out of season that breeding is attempted and the lower the normal prolificacy of the flock, the more equine serum gonadotropin that will be required.

An average dose of 500 IU / ewe is recommended as a useful starting point but doses ranging from 400 - 750 IU have been used on occasion. It is therefore recommended that accurate flock records are kept of breed, dose given, time of injection and lambs produced so that in future seasons the amount can, if necessary, be adjusted for optimum results.

Superovulation in cattle

The veterinary medicinal product may be used for the superovulation of female donor cattle prior to embryo transfer.
The following is an example, of a regime that has been successfully been applied in the field:

- A single dose of the veterinary medicinal product (1,500 - 3,000 IU) is injected between day 8 and - 13 of a normal oestrus cycle. NB: the exact dose of the veterinary medicinal product required to achieve effective superovulation will depend upon a number of factors particularly the breed, age, reproductive history, general health and nutritional status of the donor female and is subject to individual variation.

- 48 hours after injection of the veterinary medicinal product, luteolysis is induced by the injection of a prostaglandin analogue. Usually 1 ½ times the normal luteolytic dose is administered. Oestrus normally occurs approximately 48 hours after the prostaglandin injection.

- Insemination is carried out at 60 and 72 hours after prostaglandin injection.

- Collection of fertilised embryos (flushing) is carried out 6-8 days after insemination. Suitable embryos are transferred to female recipient cattle whose oestrus cycles have previously been synchronised with that of the donor female. Experience has shown that oestrus cycles in donor and recipient females should be synchronised within ± 24 hours if reasonable success is to be expected.

- A further prostaglandin treatment (usually 1 ½ times the luteolytic dose) should be administered at the time of embryo collection.

Note:

1. Despite the application of a suitable treatment regime certain individual donor cows may fail to respond.
2. Wide variations in response may be expected between individual animals. Repeated treatment of a single animal may also yield variable results.
3. The overall success of an embryo transfer protocol will be influenced by the availability of suitable equipment and the skill and experience of the operator.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitution: Reconstitute the lyophilisate with the solvent provided. . Dissolve the lyophilisate with a small quantity of solvent. Mix to obtain a homogenous solution. Transfer this solution into the vial that contains the rest of the solvent and mix until completely dissolved.

Ensure the lyophilisate has fully dissolved before use.
Use normal aseptic precautions. Avoid the introduction of contamination.

10. WITHDRAWAL PERIOD(S)

Cattle
Meat and offal: Zero days
Milk: Zero hours

Sheep
Meat and offal: Zero days
Milk: Zero hours

Pigs
Meat and offal: Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).
Keep the vials in the outer carton in order to protect from light.
The reconstituted solution should be stored in the refrigerator (2°C -8°C).

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

Shelf life after reconstitution according to directions: 24 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species

Especially in sheep, dosing of eCG should be adapted to the breed (doses should be lower in prolific breeds) and to the breeding season of animals (higher when used off season).

Special precautions for use in animals:

In case of anaphylactic shock, symptomatic treatment (e.g. adrenaline or corticosteroids) should be administered.
Where the possibility of multiple ovulations has not been excluded by clinical examination following administration of the veterinary medicinal product to uniparous species (unless to induce superovulation in cattle), it is inadvisable to permit service or to inseminate animals during the first heat produced.

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

Studies in laboratory animals exhibited teratogenic effects after the administration of eCG. Pregnant women, those intending to become pregnant, or whose pregnancy status is unknown, should not handle the product.
The veterinary medicinal product can influence fertility in humans after injection.
Administer the veterinary medicinal product with caution to avoid self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.
Accidental spillage on the skin should be washed immediately with soap and water.

Pregnancy:

Do not use during pregnancy.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

No specific treatment or antidote is recommended.

Incompatibilities:

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

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

December 2021

15. OTHER INFORMATION

Carton box containing 1 vial of 5,000 IU lyophilisate and 1 vial of solvent (25 ml).

Approved: 09/12/21