ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porceptal 4 micrograms/ml solution for injection for pigs
DK: Porceptal Vet 4 micrograms/ml solution for injection for pigs
Buserelin (as buserelin acetate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 4 micrograms of buserelin (as buserelin acetate)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 x 2.5 ml
10 x 5 ml
5 x 10 ml
5 ml
10ml
50ml

5. TARGET SPECIES

Pigs (gilts and sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by 28 days. Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Keep the vial 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

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4604

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL 2.5 ML, 5 ML, 10 ML, 50 ML VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porceptal 4 micrograms/ml solution for injection for pigs
BE: Porceptal 4 mcg/ml solution for injection for pigs
DK: Porceptal Vet 4 mikrog/ml injection for pigs
Buserelin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Buserelin 4 µg/ml

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

2.5 ml
5 ml
10 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IM, SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: Zero days

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:
Porceptal 4 micrograms/ml solution for injection for pigs

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

Marketing authorisation holder
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1A
85716 Unterschleissheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porceptal 4 micrograms/ml solution for injection for pigs
DK: Porceptal Vet 4 micrograms/ml solution for injection for pigs
Buserelin

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

Clear, colourless solution for injection containing 4.2 µg/ml buserelin acetate (corresponding to 4 µg/ml buserelin, active substance) and 20.0 mg/ml benzyl alcohol E1519 (excipient).

4. INDICATION(S)

Induction of ovulation after oestrus synchronisation by weaning (sows) or by administration of a progestin (gilts) to be used as part of a single fixed time artificial insemination program.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs (gilts and sows).

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

Single 2.5 ml (10 µg buserelin) intramuscular or subcutaneous injection per animal.
Do not pierce the stopper more than 12 times.

When treating large numbers of animals, use a suitable draw-off needle or automatic dosing syringe to avoid excessive puncturing of the closure.

9. ADVICE ON CORRECT ADMINISTRATION

The artificial insemination schedule in pigs is as follows:

Gilts:

Administer 2.5 ml product at 115-120 hours after end of the synchronisation treatment with a progestin.
A single artificial insemination should be done 30 - 33 hours after administration of the product.

Sows:

Administer 2.5 ml product at 83-89 hours after weaning.

A single artificial insemination should be done 30 - 33 hours after administration of the product.

In individual cases, it may happen that oestrus is not expressed at 30 – 33 hours after Porceptal treatment. In this case, insemination can be given later, at the moment when oestrus signs are present.

10. WITHDRAWAL PERIOD(S)

Meat and offal: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton label after “EXP”. The expiry date refers to the last day of that month.
Store in a refrigerator (2 °C - 8 °C).

Keep the vial in the outer carton in order to protect from light.

Shelf-life after first broaching the vial: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Buserelin is given after oestrus synchronisation. In gilts, buserelin is given after progestin treatment. Provided that the progestin treatment is ended simultaneously in a group of gilts, it causes a synchronisation of oestrus in the treated animals. In sows, oestrus synchronisation is achieved naturally by weaning.
Insemination can be done at 30-33 hours after buserelin injection. When using this product, the animals should be checked for signs of oestrus at the time of artificial insemination. Therefore the presence of the boar is recommended.
It may happen that negative energy balance during lactation is associated with mobilisation of body reserves with a large drop in backfat thickness (more than approximately 30 %). In such animals, oestrus and ovulation may be delayed and these animals should be managed and bred on a case by case basis.

Special precautions for use in animals:
In sows and sexually mature gilts, use of the product contrary to the recommended protocols may result in the formation of follicular cysts which may detrimentally affect fertility and prolificacy.Progestins and buserelin can only be used in healthy animals.
An aseptic technique is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Because of the hormonal effects of buserelin during pregnancy, women who are or could be pregnant should not handle the product. Women of child-bearing age should administer the product with caution.
Avoid eye and skin contact with the product. In case of accidental contact, rinse thoroughly with water.

Should skin contact with the product occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin. Wash hands after use.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke while handling the product.

Pregnancy and lactation:
The product is not indicated for use in pregnant and lactating sows.

Overdose (symptoms, emergency procedures, antidotes):
Even when the advised dose is exceeded, the occurrence of toxicity signs is unlikely as buserelin only has minor toxicity.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with 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 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

15. OTHER INFORMATION>

Pack sizes:
10 vials of 2.5 ml
10 vials of 5 ml
5 vials of 10 ml
Single vial of 5 ml
Single vial of 10ml
Single vial of 50ml
Not all pack sizes may be marketed.

Approved 14 November 2018