Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Porceptal 4 micrograms/ml solution for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:

Active substance:

Buserelin acetate	4.2 µg
(corresponding to 4 µg buserelin)	

Excipients:

Benzyl alcohol E1519	20.0 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (gilts and sows).

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Even when the advised dose is exceeded, the occurrence of toxicity signs is unlikely as Buserelin only has minor toxicity.

4.11 Withdrawal period(s)

Meat and offal: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotropin-releasing hormones
ATCvet code: QH01CA90

5.1 Pharmacodynamic properties

Buserelin is a synthetic peptide hormone with the activity analogue to the natural gonadotrophin releasing hormone (GnRH). It induces in the anterior pituitary the release of luteinising hormone (LH) and follicle stimulating hormone (FSH) into the blood. Higher amounts than the recommended clinical doses do not further stimulate LH and FSH secretion.

5.2 Pharmacokinetic particulars

After parenteral administration, buserelin is rapidly absorbed and eliminated, mainly through urine. Metabolism occurs in the liver, kidneys and pituitary. All metabolites are small inactive peptides. The LH surge occurs rapidly after injection.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol E1519
Sodium chloride
Sodium dihydrogen phosphate monohydrate
Sodium hydroxide (pH adjustment)
Concentrated hydrochloric acid (pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first broaching the vial: 28 days.

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box containing colourless glass (type I) vials of 2.5 ml, 5 ml, 10 ml or colourless glass (type II) vials of 50 ml, closed with an ETFE laminated bromobutyl rubber stopper (type I) (2.5 ml and 5 ml vials) or a bromobutyl rubber stopper (type I) (10 ml and 50 ml vials) and an aluminium crimp cap.

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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/267/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th December 2013
Date of last renewal: 5th October 2018

10 DATE OF REVISION OF THE TEXT

October 2018