

SPC

**PORCEPTAL®**

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# ANNEX I

**SUMMARY OF  
PRODUCT CHARACTERISTICS, LABELLING  
AND PACKAGE LEAFLET**



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## 1.A SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porceptal

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml:

**Active substance:**

Buserelin acetate 4.2 µg  
(corresponding to 4 µg buserelin)

**Excipients:**

Benzyl alcohol 20.0 mg  
For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

A clear, colourless solution for injection

### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Pigs (gilts and sows)

#### 4.2 Indications for use, specifying each target species

Induction of ovulation after oestrus synchronisation by weaning (sows) or by administration of a progestin (gilts) to allow a single fixed time artificial insemination.

#### 4.3 Contraindications

None.

#### 4.4 Special warnings for each target species

Porceptal is given after oestrus synchronisation. In gilts, Porceptal is given after a progestin treatment (for example, an 18 day treatment with 20mg/day altrenogest). 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.

The animals should be checked for signs of oestrus at the time of artificial insemination (30-33 hours after the Porceptal injection) preferably in the presence of a boar.

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%). First parity sows with lactation lengths below 22 days are particularly prone to negative energy balance. If this occurs in such animals, oestrus and ovulation may be delayed and such animals are not suited to the current single fixed time AI program. They should be managed and bred on a case by case basis with 2 or more AIs following detection of heat.

With the exception of the sequential use of Porceptal after a progestin in gilts, it is not recommended to use other products affecting the reproductive cycle in combination with the Porceptal treatment scheme.

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

If the recommended time schedule for Porceptal and the artificial insemination is not carefully followed, fertility may be impaired. Progestins and buserelin can only be used in healthy animals.

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

Women who are or could be pregnant should administer the product with caution.

Avoid contact with skin and eyes. Wash hands after use.

Accidental spillage on the skin should be washed off immediately with soap and water. If the preparation should by accident enter the eyes, rinse eyes with water and if necessary contact a doctor. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

#### **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 interaction**

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 single fixed-time artificial insemination schedule in pigs is as follows:

**Gilts:**

Administer 2.5 ml of Porceptal at 115-120 hours after the last dose of the synchronisation treatment with a progestin.

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

**Sows:**

Administer 2.5 ml of Porceptal at 83-89 hours after weaning.

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

In individual cases (gilts or sows), it may happen that oestrus (heat) is not expressed at 30 - 33 hours after Porceptal treatment. In such cases, check the animal for signs of oestrus twice-a-day thereafter and perform a single insemination as soon as the oestrus signs are detected.

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

The toxicity of buserelin is low. Even when the advised dose is exceeded, the occurrence of toxicity signs is unlikely.

**4.11 Withdrawal period(s)**

Meat and offal: 0 days

**5. PHARMACOLOGICAL 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 the release of luteinizing hormone (LH) and follicle stimulating hormone (FSH) from the anterior pituitary into the blood, which triggers ovulation. The surge in LH release triggered by buserelin injection induces ovulation. Higher amounts than the recommended clinical doses do not stimulate LH and FSH secretion further.

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

## 6.2 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 (2-8°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, Ph.Eur.) vials of 2.5 ml, 5 ml, 10 ml or colourless glass (type II, Ph.Eur.) vials of 50 ml, closed with a halogenatedbutyl rubber stopper (type I, Ph.Eur.) 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 product 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 International B.V.  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands



# **ANNEX II**

**PROPOSAL FOR LABELLING  
AND PACKAGE LEAFLET**



# **LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (BOX)  
CARTONBOX****NAME OF THE VETERINARY MEDICINAL PRODUCT**

Porceptal

**STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

4 micrograms of buserelin (as buserelin acetate) per ml.

**PHARMACEUTICAL FORM**

Solution for injection

**PACKAGE SIZE**

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

**TARGET SPECIES AND INDICATIONS**

Induction of ovulation after oestrus synchronisation by weaning (sows) or by administration of a progestin (gilts) to allow a single fixed time artificial insemination.

**METHOD(S) AND ROUTE(S) OF ADMINISTRATION**

I.M, I.V. Read the package leaflet before use.

**WITHDRAWAL PERIOD**

Meat and offal: 0 days

**SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**SPECIAL STORAGE CONDITIONS**

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

Once broached, use by 28 days.

#### SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

#### FOR ANIMAL TREATMENT ONLY

For animal treatment only.

#### KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

#### READ THE PACKAGE LEAFLET BEFORE USE

Read the package leaflet before use.

#### MARKETING AUTHORISATION HOLDER

Product of Intervet International B.V., Boxmeer, The Netherlands

#### BATCH NUMBER

<Batch> <Lot> <BN> <number>

#### EXPIRY DATE

<EXP month/year>

**PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS  
(SMALL LABELS) 2.5 ML, 5ML, 10 ML, 50 ML VIALS****NAME OF THE VETERINARY MEDICINAL PRODUCT**

Porceptal

**QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Buserelin 4 µg/ml

**CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

- 2.5 ml
- 5 ml
- 10ml
- 50 ml

**ROUTE(S) OF ADMINISTRATION**

I.M., S.C.

**WITHDRAWAL PERIOD**

Meat and offal: 0 days

**MARKETING AUTHORISATION HOLDER**

Product of Intervet International B.V., Boxmeer, The Netherlands

**FOR ANIMAL TREATMENT ONLY**

For animal treatment only.

**BATCH NUMBER**

<Batch> <Lot> <BN> <number>

**EXPIRY DATE**

<EXP month/year>

# PACKAGE LEAFLET



**NAME OF THE VETERINARY MEDICINAL PRODUCT**

Porceptal

**STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each ml contains 4.2 µg/ml buserelin acetate (corresponding to 4 µg/ml buserelin, active substance) and 20.0 mg/ml benzyl alcohol (excipient).

**INDICATION(S)**

Induction of ovulation after oestrus synchronisation by weaning (sows) or by administration of a progestin (gilts) to allow a single fixed time artificial insemination.

**CONTRAINDICATIONS**

None.

**ADVERSE REACTIONS**

None known.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

**TARGET SPECIES**

Pigs (gilts and sows)

**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.

**ADVICE ON CORRECT ADMINISTRATION**

The single fixed-time artificial insemination schedule in pigs is as follows:

**Gilts:**

Administer 2.5 ml of Porceptal at 115-120 hours after the last dose of the synchronisation treatment with a progestin.

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

**Sows:**

Administer 2.5 ml of Porceptal at 83-89 hours after weaning.

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

In individual cases (gilts or sows), it may happen that oestrus (heat) is not expressed at 30 - 33 hours after Porceptal treatment. In such cases, check the animal for signs of oestrus twice-a-day thereafter and perform a single insemination as soon as the oestrus signs are detected.

**WITHDRAWAL PERIOD**

Meat and offal: 0 days

**SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store in a refrigerator (2-8 °C).

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

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



## SPECIAL WARNING(S)

### Special precautions for use in animals

Porceptal is given after oestrus synchronisation. In gilts, Porceptal is given after a progestin treatment (for example, an 18 day treatment with 20mg/day altrenogest). 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.

The animals should be checked for signs of oestrus at the time of artificial insemination (30-33 hours after the Porceptal injection) preferably in the presence of a boar.

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%). First parity sows with lactation lengths below 22 days are particularly prone to negative energy balance. If this occurs in such animals, oestrus and ovulation may be delayed and such animals are not suited to the current single fixed time AI program. They should be managed and bred on a case by case basis with 2 or more AIs following detection of heat.

With the exception of the sequential use of Porceptal after a progestin in gilts, it is not recommended to use other products affecting the reproductive cycle in combination with the Porceptal treatment scheme.

If the recommended time schedule for Porceptal and the artificial insemination is not carefully followed, fertility may be impaired. Progestins and buserelin can only be used in healthy animals.

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

The toxicity of buserelin is low. Even when the advised dose is exceeded, the occurrence of toxicity signs is unlikely.

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

### User warnings

Women who are or could be pregnant should administer the product with caution.

Avoid contact with skin and eyes. Wash hands after use.

Accidental spillage on the skin should be washed off immediately with soap and water. If the preparation should by accident enter the eyes, rinse eyes with water and if necessary contact a doctor. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

## SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Any unused product or waste materials should be disposed of in accordance with local requirements.

## OTHER INFORMATION

**Not all pack sizes may be marketed.**

**For animal treatment only.**

**Product of Intervet International B.V., Boxmeer, The Netherlands**