ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OvuGel 0.1 mg/ml vaginal gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Triptorelin (as triptorelin acetate) ..... 0.1 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium methyl parahydroxybenzoate	0.9 mg
Sodium propyl parahydroxybenzoate	0.1 mg
Sodium chloride	
L-methionine	
Sodium citrate	
Citric acid anhydrous	
Methylcellulose	
Purified water	

Thin clear to slightly hazy gel.

3. CLINICAL INFORMATION

3.1 Target species

Pig (sow for reproduction)

3.2 Indications for use for each target species

For the synchronisation of ovulation in weaned sows to enable a single fixed-time artificial insemination.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use during pregnancy and/or lactation.
Do not use in sows with obvious reproductive tract abnormalities.

3.4 Special warnings

The efficacy of OvuGel has not been demonstrated in gilts (nulliparous sows), and the use of the veterinary medicinal product is therefore not recommended in these animals.

The response of sows to synchronisation protocols may be influenced by the physiological state at the time of treatment. Responses to treatment are not uniform either across herds or across individuals within herds.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The product should not be used in sows with reproductive tract abnormalities, infertility or general health disorders.

A reproduction safety study was conducted in sows after administration of 3 times the recommended dose of Ovugel and did not show any effect on reproduction performance nor on the piglets. However, safety of treatment in sows in subsequent reproductive cycles has not been demonstrated. Potential long-term effects of cyst occurrence cannot be excluded.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product can cause eye irritation. People with known hypersensitivity to GnRH analogues or any of the excipients (including parabens) should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of overalls and gloves should be worn when handling the veterinary medicinal product.
Do not eat, drink or smoke while handling the veterinary medicinal product.
Avoid direct contact with skin or eyes, wash hands after handling the veterinary medicinal product.
In case of accidental contact with the eyes, rinse thoroughly and seek medical advice immediately.
In case of accidental skin contact, wash contaminated areas with soap and water.
Triptorelin can affect reproductive cycles in women and the effects of accidental exposure in pregnant women are unknown; therefore, it is recommended that pregnant women should not handle the veterinary medicinal product, and that women of child-bearing age should handle the veterinary medicinal product with caution.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy and lactation:
Do not use during pregnancy and/or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.
No data available.

3.9 Administration routes and dosage

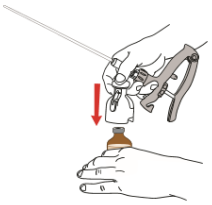
For vaginal use.

Each sow should receive a single 2 ml dose (equivalent to 0.2 mg) of the product intravaginally using a commercially available self-filling syringe with a draw-off needle, designed to deliver accurately doses of 2 ml and on which an intravaginal infusion tube can be plugged.

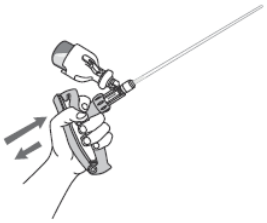
OvuGel should be administrated intravaginally at 96 hours ± 2 hours after weaning.

Sows should be inseminated approximately 22 hours ± 2 hours following administration of the veterinary medicinal product.

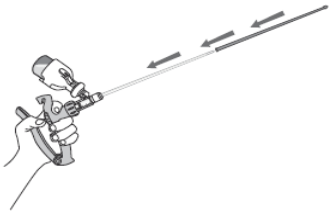
1. Allow the vial to warm to room temperature for a minimum of 10 minutes.

2. 

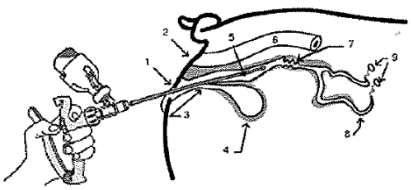
Remove foil tab from top of the vial. Keep the vial in the upright position, invert the applicator over and push it onto vial.

3. 

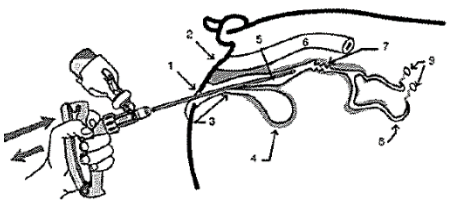
Slowly compress and release the applicator handle causing the veterinary medicinal product to enter the infusion tube and another dose from the vial to refill the chamber. This allows also to displace any air in the infusion tube

4. 

Use a disposable protective sheath for each individual sow.

5. 

Gently and slowly insert the infusion tube into the vagina at a slight upper angle (to avoid entry into the urethra) until you encounter mild resistance (the cervix) and then withdraw the infusion tube approximately 1-3 cm.

6. 

Discharge the veterinary medicinal product dose into the vagina and remove the infusion tube from the vagina.

1-vulva
2-anus
3-urethra
4-bladder
5-vagina
6-rectum
7-cervix
8-uterine horn
9-ovaries

The number of doses per vial will depend on the practices in the field, including the type of device and the regime of administration.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Administration of the veterinary medicinal product in gilts and sows at doses up to 3X the recommended dose daily for 3 consecutive days showed the presence of luteal cysts in the ovaries, the maximal incidence being observed at 3 times the dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QH01CA97

4.2 Pharmacodynamics

Triptorelin is a synthetic analogue of GnRH.
GnRH is synthesised in and secreted from the hypothalamus and targets the anterior pituitary gland where it stimulates the release of luteinizing hormone (LH) and follicle stimulating hormone (FSH). These in turn stimulate the production of sex steroids and gametogenesis (ovulation). The hypothalamic release of GnRH is controlled by biofeedback from the circulating sex steroid hormones.
The mode of action of triptorelin is the same as for natural GnRH. GnRH interacts with its plasma membrane bound gonadotropin releasing hormone receptors expressed on the pituitary gonadotrope cells. This in turn activates the mobilisation of calcium and via a G-protein, the activation of a phospholipase C-type enzyme. The subsequent accumulation of calcium activates calmodulin, which appears to mediate the release of gonadotropins.
In sows, 48 hours after the intravaginal application of 0.2 mg of triptorelin, ovulation was observed in 78 to 81% of animals.
The expected secondary pharmacodynamics effects following chronic parenteral administration are pituitary desensitisation followed by gonadal suppression resulting in reduction of serum sex steroids. This has been observed following use in human medicine.

4.3 Pharmacokinetics

In the target animal, blood levels of triptorelin were substantially higher after intravenous administration, than those following intravaginal administration. Quantifiable levels were detectable after 12 hours following intravenous administration in comparison to 6 hours following intravaginal administration.
AUC_{last} values in sows indicated that the exposure to triptorelin was 13 x lower after intravaginal administration relative to intravenous administration of the same dose. Less than 7.45% of the triptorelin dose was absorbed through the vaginal mucosa following administration of 0.2 mg of triptorelin in the form of the veterinary medicinal product.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
After first opening, do not store above 25 °C.

5.4 Nature and composition of immediate packaging

A multidose 50 ml type I amber glass vial closed with a bromobutyl rubber stopper and an aluminium seal.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER

EU/2/20/260/001

8. DATE OF FIRST AUTHORISATION

10/11/2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OvuGel 0.1 mg/ml vaginal gel

2. STATEMENT OF ACTIVE SUBSTANCES

Triptorelin (as triptorelin acetate) 0.1 mg/ml

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Pig (sow for reproduction)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Vaginal use

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within: 28 days.

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
After first opening, do not store above 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/20/260/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OvuGel 0.1 mg/ml vaginal gel

2. STATEMENT OF ACTIVE SUBSTANCES

Triptorelin (as triptorelin acetate)…….0.1 mg/ml

3. TARGET SPECIES

Pig (sow for reproduction)

4. ROUTES OF ADMINISTRATION

Vaginal use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within: 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
After first opening, do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

OvuGel 0.1 mg/ml vaginal gel

2. Composition

Each ml contains:

Active substance:
Triptorelin (as triptorelin acetate) ..... 0.1 mg

Excipients:
Sodium methyl parahydroxybenzoate ..... 0.9 mg
Sodium propyl parahydroxybenzoate ..... 0.1 mg

Thin clear to slightly hazy gel.

3. Target species

Pig (sow for reproduction)

4. Indications for use

For the synchronisation of ovulation in weaned sows to enable a single fixed-time artificial insemination.

5. Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use during pregnancy and/or lactation.
Do not use in sows with obvious reproductive tract abnormalities.

6. Special warnings

Special warnings :
The efficacy of the product has not been demonstrated in gilts (nulliparous sows), and the use of the product is therefore not recommended in these animals.
The response of sows to synchronisation protocols may be influenced by the physiological state at the time of treatment. Responses to treatment are not uniform either across herds or across individuals within herds.

Special precautions for safe use in the target species:
The product should not be used in sows with reproductive tract abnormalities, infertility or general health disorders.

A reproduction safety study was conducted in sows after administration of 3 times the recommended dose of Ovugel and did not show any effect on reproduction performance nor on the piglets. However, safety of treatment in sows in subsequent reproductive cycles has not been demonstrated. Potential long-term effects of cyst occurrence cannot be excluded.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product can cause eye irritation. People with known hypersensitivity to GnRH analogues or any of the excipients (including parabens) should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of overalls and gloves should be worn when handling the veterinary medicinal product.
Do not eat, drink or smoke while handling the veterinary medicinal product.
Avoid direct contact with skin or eyes, wash hands after handling the veterinary medicinal product.
In case of accidental contact with the eyes, rinse thoroughly and seek medical advice immediately.
In case of accidental skin contact, wash contaminated areas with soap and water.
Triptorelin can affect reproductive cycles in women and the effects of accidental exposure in pregnant women are unknown; therefore, it is recommended that pregnant women should not handle the veterinary medicinal product, and that women of child-bearing age should handle the veterinary medicinal product with caution.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.
Do not use during pregnancy and/or lactation.

Overdose:Administration of the veterinary medicinal product in gilts and sows at doses up to 3X the recommended dose daily for 3 consecutive days showed the presence of luteal cysts in the ovaries, the maximal incidence being observed at 3 times the dose.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:{national system details}.

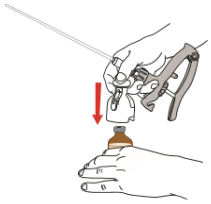
8. Dosage for each species, routes and method of administration

Each sow should receive a single 2 ml dose (equivalent to 0.2 mg) of the product intravaginally using a commercially available self-filling syringe with a draw-off needle, designed to deliver accurately doses of 2 ml and on which an intravaginal infusion tube can be plugged.
OvuGel should be administered intravaginally at approximately 96 hours after weaning.
Sows should be inseminated approximately 22 hours ± 2 hours following administration of the product using standard artificial insemination techniques.
The number of doses per vial will depends on the practices in the field, including the type of device and the regime of administration.

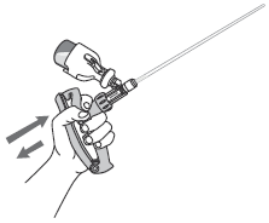
9. Advice on correct administration

OvuGel should be administrated intravaginally at 96 hours ± 2 hours after weaning.

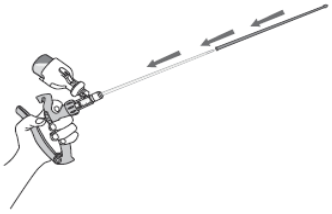
The veterinary medicinal product should be warmed to room temperature for 10 minutes prior to use.

1. 

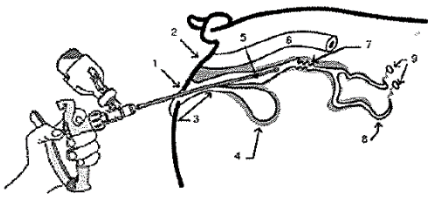
Remove foil tab from top of the vial. Keep the vial in the upright position, invert the applicator over and push it onto vial.

2. 

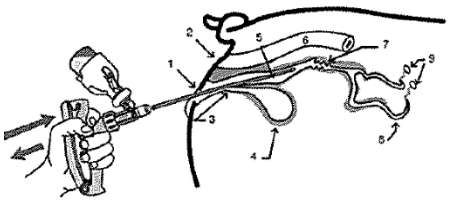
Slowly compress and release the applicator handle causing the veterinary medicinal product to enter the infusion tube and another dose from the vial to refill the chamber. This allows also to displace any air in the infusion tube

3. 

Use a disposable protective sheath for each individual sow.

4. 

Gently and slowly insert the infusion tube into the vagina at a slight upper angle (to avoid entry into the urethra) until you encounter mild resistance (the cervix) and then withdraw the infusion tube approximately 1-3 cm.

5. 

Discharge the veterinary medicinal product dose into the vagina and remove the infusion tube from the vagina.

1-vulva
2-anus
3-urethra
4-bladder
5-vagina
6-rectum
7-cervix
8-uterine horn
9-ovaries

The number of doses per vial will depend on the practices in the field, including the type of device and the regime of administration.

10. Withdrawal periods

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).
After first opening, do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and the 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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/20/260/001

Box with 1 vial of 50 ml.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

Local representatives and contact details to report suspected adverse reactions:
Vetoquinol S.A.
Magny-Vernois
70200 Lure
France
Tel: +33 3 84 62 55 55