[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Busol 0.004 mg/ml solution for injection for cattle, horses, rabbits BE, BG, CY, CZ, EL, ES, HR, HU, IE, IS, PT, RO, SI, SK
Busol vet 0.004 mg/ml solution for injection for cattle, horses, rabbits FI
Ovulike 0.004 mg/ml solution for injection for cattle, horses, rabbits EE, IT, LV, LT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Buserelin (as Buserelin acetate) 0.004 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	20.0 mg
Sodium chloride	
Sodium dihydrogen phosphate dihydrate	
Sodium hydroxide (for pH adjustment)	
Water for injections	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, rabbits.

3.2 Indications for use for each target species

Cows:
Induction of ovulation in cows with a dominant follicle.
Synchronisation of oestrus and induction of ovulation.
Treatment of ovarian follicular cysts.

Mares:
Induction of ovulation in oestrus mares.
Improvement of pregnancy rate.

Female rabbits:
Ovulation induction at post partum insemination.
Improvement of conception rate.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or any of the excipients.

3.4 Special warnings

Treatment with a Gonadotropin releasing hormone (GnRH) analogue is only symptomatic; the causes underlying a fertility disorder are not eliminated by this treatment.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid eye and skin contact with the solution for injection. In case of accidental eye contact, rinse thoroughly with water. Should skin contact with the veterinary medicinal product occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin.
When administering the veterinary medicinal product, care should be taken to avoid accidental self-injection by ensuring that animals are suitably restrained and the application needle is shielded until the moment of injection. Because of the potential for effects on reproductive function, women of child-bearing age should handle the veterinary medicinal product with caution. The veterinary medicinal product should not be administered by pregnant women. 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 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, the local representative, or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be administered to animals at any stage of pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular use (cattle, horses, rabbits), intravenous use (horses) or subcutaneous use (horses, rabbits).

Species / Indication	mg Buserelin	ml Busol
Cows		
Induction of ovulation in cows with a dominant follicle	0.01	2.5
Synchronisation of oestrus and induction of ovulation when used as follows: Buserelin administration (Day 0), followed by PGF2α treatment after seven days (Day 7) and a second buserelin treatment after nine days (Day 9).	0.01	2.5
Treatment of ovarian follicular cysts	0.02	5.0
Mares		
Induction of ovulation in oestrus mares when administered repeatedly at 12 h intervals	0.02 – 0.04	5 – 10
Improvement of pregnancy rate when administered between 8 and 12 days after natural mating / insemination	0.02 – 0.04	5 – 10
Female rabbits		
Induction of ovulation for post-partum insemination	0.0008	0.2
Improvement of conception rate	0.0008	0.2

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

No specific overdose reactions known.

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

Cattle, horses, rabbits
Meat and offal: Zero days

Cattle, horses
Milk: Zero days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QH01CA90

4.2 Pharmacodynamics

Buserelin is a peptide hormone which is chemically analogous to the releasing hormone (RH) of the luteinising hormone (LH) and follicle stimulating hormone (FSH) thus a Gonadotropin releasing hormone (GnRH) analogue.
The mode of action of Buserelin corresponds to the physiologic-endocrinological action of the naturally occurring gonadotrophin releasing hormone.
GnRH leaves the hypothalamus via the hypophyseal portal vessels and enters the anterior lobe of the hypophysis. Here it induces the secretion of the two gonadotrophins FSH and LH into the peripheral blood stream. These then act physiologically to cause maturation of ovarian follicles, ovulation and lutenization in the ovary.

4.3 Pharmacokinetics

Buserelin is rapidly eliminated from the plasma after intravenous administration, its initial half-life being 3 - 4.5 minutes in rats and 12 minutes in guinea pigs. It accumulates in liver, kidneys, and hypophysis; high concentrations being found in hypophyseal tissue after about 60 minutes. The inactivation of buserelin by enzymatic breakdown (peptidases) can be demonstrated in the hypothalamus and hypophysis and in liver and kidneys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:	2 years.
Shelf life after first opening the immediate packaging:	28 days.

5.3 Special precautions for storage

Do not store above 25 °C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Clear glass (type I) vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap.

Pack size:
5 vials of 10 ml in a cardboard box
Multipack sizes:
50 (10x5) vials of 10 ml in a cardboard box
100 (20x5) vials of 10 ml in a cardboard box
250 (50x5) vials of 10 ml in a cardboard box
500 (100x5) vials of 10 ml in a cardboard box

Not all pack sizes may be marketed.

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

T.P. Whelehan Son & Co. Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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).