Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Busol 0.004 mg/ml solution for injection for cattle, horses, rabbits

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance

Buserelin (as Buserelin acetate)	0.004 mg/ml

Excipient(s)

Benzyl alcohol (E1519)	20.0 mg/ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless liquid

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, horse, rabbit

4.2 Indications for use, specifying the target species

Cow:
Induction of ovulation in cows with a dominant follicle.
Synchronisation of oestrus and induction of ovulation.
Treatment of ovarian follicular cysts.
Mare:
Induction of ovulation in oestrus mares.
Improvement of pregnancy rate.
Rabbit:
Ovulation induction at post partum insemination.
Improvement of conception rate.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals
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 product occur, wash the exposed area immediately with soap and water, as GnRH analogues may be absorbed through the skin.
When administering the 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 product with caution. Pregnant women should not administer the product. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For intramuscular (cattle, horses, rabbits), intravenous (horses) or subcutaneous (horses, rabbits) administration.

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 hour 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
Rabbit		
Induction of ovulation for post-partum insemination	0.0008	0.2
Improvement of conception rate	0.0008	0.2

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

No specific overdose reactions known.

4.11 Withdrawal period(s)

Cattle, horses, rabbits
Meat and offal: Zero days

Cattle, horses
Milk: Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Gonadotropin-releasing hormone, ATCvet code: QH01CA90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Sodium chloride
Sodium dihydrogen phosphate dihydrate
Sodium hydroxide
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 opening the immediate packaging: 28 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Pack of 5 injection vials (glass type I) each containing 10 ml in a cardboard carton
Pack of 50 (10x5) injection vials (multipack)
Pack of 100 (20x5) injection vials (multipack)
Pack of 250 (50x5) injection vials (multipack)
Pack of 500 (100x5) injection vials (multipack)

Injection vials closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

T.P. Whelehan Son & Co. Ltd.,
Bracetown Business Park
Clonee
Co. Meath
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10953/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first Authorisation: 05 September 2008
Date of last renewal: 29 August 2013

10 DATE OF REVISION OF THE TEXT

December 2014