

DALMARELIN

COMPOSITION:

1 ml contains:

Active substance:

Lecirelin acetate equivalent to lecirelin 0.0262mg/ml

Excipients:

Benzyl alcohol 20mg/ml

Other excipients and water for injections q.s. to 1ml

Injectable solution

Pharmacological Properties and Pharmacokinetic Particulars:

Pharmacodynamic particulars

DALMARELIN is a solution for injection based on lecirelin, a synthetic analogue of gonadotropin releasing hormone (GnRH).

Lecirelin (compared with natural GnRH) has substituted glycine residue in position 7 rather than a D-tert-leucine residue. In addition GnRH is a decapeptide, whereas lecirelin is a nonapeptide, resulting from the substitution of glycine in position 10 with an ethylamide group.

The biological action of lecirelin is comparable to that of natural GnRH. After parenteral administration, the peptide binds to specific receptors of the anterior lobe of the hypophysis, with consequent increase in release and synthesis of the gonadotropins LH and FSH. The physiological action of the gonadotropins results from stimulating the maturation of the follicle, inducing ovulation and the appearance of corpora lutea in the ovary.

Due to structural difference between lecirelin and natural GnRH, the lecirelin molecule shows greater persistence at the site of the specific hypophyseal receptors, with consequent increased secretion of LH and FSH.

Pharmacokinetic particulars

Lecirelin, administered by the intramuscular route, is rapidly absorbed in all animal species.

Plasma elimination occurs rapidly, whilst the hormonal action persists for several hours, because of binding to specific hypophyseal receptors.

However, distribution and elimination are species and dose dependant.

Plasma clearance times of approximately 40 and 60 minutes are observed in cattle and rabbits, respectively.

GnRH-analogues accumulate primarily in the liver, kidney and hypophysis whereupon they are metabolised enzymatically, producing compounds devoid of pharmacological activity, which are subsequently excreted in the urine.

PHARMACEUTICAL PARTICULARS

Major incompatibilities

Highly alkaline solutions.

Indications:

Indications for use

Cattle: Treatment of follicular ovarian cysts. Improvement of the fertility in the early post-partum phase. Induction of ovulation in cows with regular or irregular cycling or for initiating the resumption of ovarian cycle in acyclic cows. Short or silent heats and prolonged heats. Prevention of delayed ovulation and ovulation synchronisation at the time of artificial insemination.

Horses: Induction of ovulation. Treatment of anestrus.

Contra-indications

None.

Undesirable effects

None observed.

Special precautions for use

Follow the normal procedures for aseptic administration.

Use during pregnancy and lactation

DALMARELIN should not be used in pregnant animals as it is a synthetic reproductive hormone. However, no contraindications are known for GnRH and its analogues.

Interactions with other medicaments and other forms of interaction

Not known.

DALMARELIN (cont)

Dosage and Method of Administration:

Administer by the intramuscular route.

The dosage varies according to the indications and the animal species, as follows:

Cattle

Treatment of follicular ovarian cysts

For the treatment of cysts, 4ml.

Improvement of the fertility in the early post-partum phase 2ml

Induction of ovulation in cows with regular or irregular cycling or for initiating the resumption of ovarian cycle in acyclic cows: 2ml.

In cases where ovarian activity is not observed in the 10-12 day period following treatment, repeated treatment is indicated.

Short or silent heats and prolonged heats 2ml.

Prevention of delayed ovulation and ovulation synchronisation at the time of artificial insemination 2ml.

Horses

Induction of ovulation 4ml.

Administration is performed when, after rectal or ultrasound examination, a follicle of a diameter greater than 35mm is observed.

Treatment may be repeated if, after a period of 24-36 hours, ovulation does not occur.

Treatment of anestrus 4ml.

Overdose (symptoms, emergency procedures, antidotes)

No adverse reactions were recorded in cattle and horses with up to 10, 3 and 2 times the recommended dose, respectively.

Special warnings for each target species

None.

Withdrawal periods

Milk: 0 hours

Meat: 0 days

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

GnRH-analogues may be absorbed through intact skin. In case of dermal contact, wash the exposed area immediately with soap and water.

Storage, Shelf Life, Disposal:

Shelf-life

2 years, for correctly stored, sealed product.

After first opening of the vial, use the product within 28 days.

Special precautions for storage

Store at a temperature not exceeding 25°C.

Nature and contents of container

20ml type I or type II glass vials, or 100ml plastic HDPE, closed with a rubber stopper and an aluminium overseal.

Special precautions for the disposal of unused product or waste materials, if any

Do not litter.

Dispose of empty containers in accordance with local requirements.

Unused product must be taken to the usual collection points for expired or unused pharmaceuticals

Manufactured by and registered by:
FATRO S.P.A. Industria Pharmaceutica Veterinaria
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(Bologna) Italy

Registered pursuant to the ACVM Act 1997,
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RESTRICTED VETERINARY MEDICINE

Dalmarelin

For Animal Treatment Only

Website: www.nzfsa.govt.nz/acvm

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