

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fertagyl 0.1 mg/ml Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Gonadorelin Acetate

Equivalent to gonadorelin 0.1 mg

Excipients

Benzyl Alcohol 10 mg

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless, aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

It may be used in breeding cattle:

- for the treatment of cystic ovaries
- prior to treatment with a prostaglandin for the induction of oestrus
- in association with AI to optimise the time of ovulation, improving the conception rate
- in the early post-partum period to initiate normal ovarian activity

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Care should be taken to avoid accidental self-injection. In the event of accidental self-injection, seek medical advice immediately.

The veterinary medicinal product should not be administered by pregnant women.

Accidental splashes in the eyes should be washed with plenty of water.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not indicated for use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Treatment of cystic ovaries: 0.5 mg (5 ml)
 Other indications: 0.25 mg (2.5 ml)

Administer by deep intramuscular injection observing the normal aseptic precautions. Sterile equipment should be used for administration, but avoid contamination of product with traces of disinfectant or spirit.

Cystic ovaries: the presence of ovarian cysts may result in irregular return to oestrus or nymphomania. Anoestrus may be observed. The condition is diagnosed by rectal palpation revealing the presence of persisting follicular structures with a diameter over 2.5 cm, and should be confirmed by the use of plasma or milk progesterone assay. A single dose of 5 ml Fertagyl should be given. Breeding cattle may be inseminated on the oestrus following treatment (20 - 22 days post injection). If short, irregular oestrus intervals persist, a second treatment may be administered. If oestrus is not observed by 14 days from the initial Fertagyl treatment, prostaglandin should be administered.

Use with prostaglandin for oestrus induction

A single injection of 2.5 ml Fertagyl should be given 7 days prior to the administration of prostaglandin. A further injection of 2.5 ml Fertagyl should be given prior to service as indicated under "Use in conjunction with AI" below.

Use in conjunction with AI:

The success of AI is dependent on the proper timing of insemination relative to the time of ovulation. A single injection of 2.5 ml Fertagyl on the day of AI has been shown to increase conception rates, particularly in repeat breeder cattle (i.e. animals on the 3rd subsequent service) and in animals with a body condition score <3.

Where a GnRH/prostaglandin regime is used to induce ovulation for fixed time service, cows should be given 2.5 ml Fertagyl 54-56 hours after the prostaglandin treatment and served 72 hours after prostaglandin (16 - 18 hours after Fertagyl). If cows are observed in oestrus before 56 hours, necessitating service before 72 hours, they should be served at oestrus and Fertagyl administered at or before the service.

Use in the post-partum cow:

Many cows have resumed ovarian cyclicity by 30 days post-partum. A significant number do however remain acyclic and these would benefit from an early intervention using GnRH to initiate a resumption of ovarian activity. Cows with a history of slow resumption of cyclicity in one lactation tend to be slow again in subsequent lactations and may be identified from individual cow/herd records. An injection of 2.5 ml Fertagyl in the early post-partum period (<40 days) helps maintain an optimal calving to first service interval and may result in an improved conception rate to first service.

Further information

The use of Fertagyl 7 days prior to prostaglandin increases the proportion of cows able to respond to the prostaglandin and co-ordinates a new follicular wave so more cows will ovulate during a shorter time after prostaglandin. A second Fertagyl treatment after the prostaglandin further tightens synchrony of ovulation in relation to the service time.

The GnRH/prostaglandin/GnRH regime (Intercept) for breeding dairy cows at a pre-planned time without the need for specific heat detection is summarised below:

Day 0	Fertagyl 2.5 ml	
Day 7 (a.m.)	prostaglandin*	
Day 9 (p.m.)	Fertagyl 2.5 ml	54-56 hours post prostaglandin or at AI if sooner.
Day 10 (a.m.)	AI	72 hours post prostaglandin or at observed heat if sooner.

* e.g. 2 ml Prosolvin (Intervet)

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

No specific treatment or antidote recommended.

4.11 Withdrawal Period(s)

Meat and offal: Zero days

Milk: Zero hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Gonadorelin, the active ingredient of Fertagyl, is a synthetic GnRH with a structure identical to that of the naturally occurring hormone. Administration results in the release of both LH and FSH from the anterior pituitary gland. As FSH and LH play a key role in the final maturation of the preovulatory follicle, gonadorelin has the ability to induce and synchronise ovulation, induce turnover of the cystic follicles and improve conception rate.

5.2 Pharmacokinetic properties

After intra-muscular administration in cows, gonadorelin is rapidly absorbed from the injection site, with a plasma half-life of approximately 20 minutes. The compound is rapidly metabolised to smaller peptides and amino acids, which are mainly excreted in urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride

Benzyl alcohol

Acetic acid solution

Sodium hydroxide solution

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 opening the immediate packaging: 24 hours at +2-8°C

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

5ml clear, glass Type I (Ph. Eur.) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/022/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

January 2014