SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chronogest CR 20mg controlled release vaginal sponge for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sponge contains:

Active substance:
17,9 mg flugestone equivalent to 20 mg flugestone acetate.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Hydroxypropylcellulose	20 mg
Macrogol 4000	20 mg

White cylindrical polyester polyurethane medicated sponge equipped with string.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (ewe and ewelamb).

3.2 Indications for use for each target species

In ewes and ewe lambs, in combination with PMSG (Pregnant Mare Serum Gonadotropin)

- Induction and synchronization of oestrus and ovulation (non cycling ewes during seasonal anoestrus and ewe lambs).
- Synchronization of oestrus and ovulation (cycling ewes and ewe-lambs).

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

- The repeated treatment with the product combined with PMSG may trigger the appearance of PMSG antibodies in some ewes. This in turn may affect the time of ovulation and result in reduced fertility when combined with fixed time artificial insemination at 55h following sponge removal.
- The repeated use of sponges within one year has not been studied.
- The use of a vaginal applicator designed for ewes or ewe lambs is recommended to correctly insert sponges and to avoid vaginal injuries.

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

Personal protective equipment consisting of single use gloves should be worn when handling the veterinary medicinal product.
The veterinary medicinal product should not be administered by pregnant women or women suspected to be pregnant.

Direct contact with the skin should be avoided.

If accidental contact with the skin occurs, wash the affected zone with soap and water.
Wash hands
after treatment and before meals.
Human exposure to this product can affect fertility.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep (ewe and ewe lamb).

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vaginal discharge[1]

[1] muco-purulent discharge may be observed at sponge removal. It is not associated with clinical signs and does not alter fertility.

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 “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The use is not recommended during pregnancy.
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

The sponges should not be used in conjunction with alcohols, cresols, phenols, sheep dips or similar disinfectants.

3.9 Administration routes and dosage

The dose is one sponge per animal irrespective of body weight, breed, type (dairy or meat) and season.
The sponge is inserted intra-vaginally using an applicator.
Duration of sponge residence is 14 days. At the end of the administration period, the sponge is gently removed by pulling on its string.
To obtain an optimal synchronization of ovulation, an intra-muscular injection of PMSG (range 300-700 IU) is recommended (i.m.) at the time of sponge removal.
In case fixed time artificial insemination is applied, it is recommended to perform it 55 h after sponge removal.

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

A five time overdose of flugestone acetate (100 mg/sponge) did not result in observable side effects.

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: 2 days after withdrawal of sponges.
Milk: zero hours, including the treatment time.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG03D

4.2 Pharmacodynamics

Flugestone acetate is a synthetic analogue of progesterone. It is approximately 20 fold more potent than progesterone and displays progestational activity but no anti-progestational, anti-androgenic or androgenic properties together with a low glucocorticoid activity.

Owing to its binding to the progesterone receptors, flugestone acetate acts by negative feed back on the hypothalamo-pituitary axis, suppressing pituitary release of gonadotropins and therefore terminal follicular growth and ovulation.

4.3 Pharmacokinetics

Flugestone acetate is readily absorbed during the 12-14 days period of intra-vaginal administration. T_{max} ranges between 8 and 24 h, whereas C_{max} varies between 1.4 and 3.7 ng/ml. Steady state is reached quickly following onset of the treatment. Plasma cronolone concentrations are relatively constant throughout treatment. One day after removal of the Chronogest CR, flugestone acetate concentrations have dropped below the limit of quantification (LOQ = 0.04 ng/mL).

Flugestone acetate is metabolised into hydroxylated metabolites, which are excreted in faeces and urine.

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.

5.3 Special precautions for storage

Store below 25 °C.
Store in the original package.
Store in a dry place.
Once packaging is opened, any unused product should be discarded.

5.4 Nature and composition of immediate packaging

Not all pack sizes may be marketed.

Bags made of polyester/ aluminium/ polyethylene containing 10 sponges, 25 sponges or 50 sponges.

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

Intervet International B.V.
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 06376/3003

8. DATE OF FIRST AUTHORISATION

21 June 2005

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

June 2024

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).