SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chronogest CR 20 mg 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:

Hydroxypropylcellulose	20 mg
Macrogol 4000	20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White cylindrical polyester polyurethane medicated sponge equipped with string.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep (ewe and ewe lamb).

4.2 Indications for use, specifying the 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).

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

- 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.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amount(s) to be administered and administration route

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.

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

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

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: progestagen.

ATCvet code: QG03D

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropylcellulose
Macrogol 4000

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 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.

6.5 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5087

9. DATE OF FIRST AUTHORISATION

21 June 2005.

10. DATE OF REVISION OF THE TEXT

October 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk

Approved 10 January 2024