SYNCROPART® SPONGES

Product information

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syncropart 30mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Flugestone acetate..... 30 mg

Excipient q.s. 1 vaginal sponge

For the full list of excipients, see section 6.1. “List of excipients”.

3. PHARMACEUTICAL FORM

Vaginal sponge.

4. CLINICAL PARTICULARS

4.1 | Target species

Sheep (ewes and ewe-lambs).

4.2 | Indications for use, specifying the target species

In ewes and ewe-lambs, in combination with eCG:

- Induction and synchronization of heat and ovulation at the anoestrus season (non-cycling ewes and sexually mature ewe-lambs).
- Synchronisation of heat and ovulation in the sexual season (cycling ewes and sexually mature ewe-lambs).

4.3 | Contraindications

The use of the veterinary medicinal product in pregnant females is contraindicated.

4.4 | Special warnings for each target species

None.

4.5 | Special precautions for use

i Special precautions for use in animals

Repeated treatments with the veterinary medicinal product in combination with eCG may lead to the appearance of anti-eCG antibodies in some ewes. This can change the timing of ovulation and lead to decreased fertility when treatment is combined with artificial insemination. Repeated use of the veterinary medicinal product in the same year has not been studied.

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

Direct contact with the skin should be avoided. Wear disposable gloves when handling and fitting sponges. In case of accidental skin contact, wash the affected area with soap and water. Wash hands after treatment and before eating. The fertility of people exposed to this product may be affected. Women who are pregnant or likely to become pregnant should not handle the product.

iii Other precautions

None.

4.6 | Adverse reactions (frequency and seriousness)

Muco-purulent discharge can sometimes be observed when the sponge is removed. It is not associated with clinical signs and does not impair fertility.

4.7 | Use during pregnancy, lactation or lay

The veterinary medicinal product can be used during lactation.
The use of the veterinary medicinal product during pregnancy is not recommended.

4.8 | Interaction with other medicinal products and other forms of interaction

Not known.

4.9 | Amounts to be administered and administration route

Vaginal route.
Sheep: a sponge left in place for 14 days.

Insertion:
The sponge is placed at the bottom of the vagina using an applicator provided for this purpose. Insert the sponge through the bevelled end of the applicator, string first. Clean the vulva, spread the labia of the vulva, and gently introduce the applicator to the bottom of the vagina. Release the sponge by sliding the applicator over the plunger which is held still. The applicator should be thoroughly cleaned and disinfected between each application with a non-irritating disinfectant solution (quaternary ammonium). The sponge remains in place for 14 days.

Removal:
The sponge is removed by gently pulling the string. To achieve optimal synchronisation of ovulation, an injection of eCG (from 300 to 600 IU depending on the breed and physiological state of the females and the season of treatment) is administered intramuscularly at the time of sponge removal.

Fertilisation:
Fertilisation can be carried out by natural mating in the presence of a ram, or "in hand" ie at a determined time (48 hours and 60 hours after removal). Artificial insemination can be performed 55 hours after removal of the sponge in ewes or 51 hours after removal of the sponge in ewe-lambs.

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

Not known.

4.11 | Withdrawal period

Meat and offal: 5 days after sponge removal.
Milk: zero days, including during sponge presence.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: progestagens.
ATCvet code: QG03D

5.1 | Pharmacodynamic properties

Flugestone acetate is a synthetic analogue of progesterone. It is approximately 20 times more potent than progesterone and exhibits progestogen activity as well as mild glucocorticoid activity but no anti-progestin, anti-androgenic or androgenic properties. By binding to progesterone receptors, flugestone acetate acts by negative feedback on the hypothalamic-pituitary axis, suppressing the release by the pituitary gland of gonadotropins thus preventing the appearance of heat and ovulation while sensitizing the ovarian receptors of the animal. The removal of the sponge causes the cessation of this progestin-only impregnation and the initiation of a follicular phase thus causing terminal follicular growth and ovulation.

5.2 | Pharmacokinetic particulars

Flugestone acetate is readily absorbed during the 14-day period of intravaginal administration. Flugestone acetate plasma concentrations are relatively constant during treatment. Flugestone acetate is metabolized to hydroxylated metabolites that are excreted in faeces and urine.

6. PHARMACEUTICAL PARTICULARS

6.1 | List of excipients

Polyurethane foam pad

6.2 | Incompatibilities

Not known.

6.3 | Shelf life

3 years.
After opening: unused sponges should be discarded.

6.4 | Special precautions for storage

Store away from light and moisture.

6.5 | Nature and composition of immediate packaging

Metallized polyester / polyethylene bag containing 25 sponges.

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

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