

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Morlam Intravaginal Sponge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sponge contains:

Medroxyprogesterone Acetate 60 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Vaginal sponge.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

The induction and synchronisation of oestrus in late anoestrus and the normal breeding season.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Animals in poor condition, whether from illness, inadequate nutrition or other factor, may respond poorly to treatment.

The sponge treatment is not a substitute for good husbandry and management and will not correct fertility or improve fertility in barren ewes.

4.5 Special precautions for use

Special precautions for use in animals

Sponges should only be inserted by means of the special applicator provided. The applicator should be cleaned between each application, using an antiseptic suitable for application to body tissues, used according to label recommendations.

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

For reasons of hygiene and to avoid the possibility of percutaneous absorption of progestagen, disposable plastic gloves should be worn when administering and removing the Morlam sponge.

4.6 Adverse reactions (frequency and seriousness)

Signs of local irritation are rare but a vaginal discharge may occur. This should resolve spontaneously after removal of the

sponge.

4.7 Use during pregnancy, lactation or lay

Progesterone plays an important physiological role during pregnancy by maintaining the secretory function of the corpus luteum. Sponges inserted into pregnant animals will not compromise the pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The Morlam sponge is for intravaginal administration only. The Morlam sponge is administered by means of a special speculum and rod. Insertion involves gentle cleaning of the vulva and perineum before gently inserting the applicator into the vagina. The sponge is expelled by pushing the plunger rod as the applicator is withdrawn, leaving the withdrawal filament protruding at the vulva. A single Morlam sponge containing 60 mg Medroxyprogesterone acetate is inserted in the vagina of each ewe to be treated. The sponge is left in position for 12 -14 days.

During the anoestrus period a single injection of 500 - 750 iu of pregnant mares serum Gonadotrophin (PMSG) is administered at sponge removal. During the normal breeding season PMSG is not required for synchronisation, unless an increase in ovulation rate and litter size is the aim.

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

Not applicable.

4.11 Withdrawal Period(s)

Edible tissues from slaughtered animal: 5 days. Animals should not be slaughtered for human consumption during the period of treatment and for five days after withdrawal of the sponges.

Milk: Milk from treated animals should not be used for human consumption during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Progestogens, pregnen (4) derivatives

ATCvet code: QG03DA02

5.1 Pharmacodynamic properties

Medroxyprogesterone acetate is released from the impregnated sponge and absorbed in to the blood stream of the animal, to mimic the release of progesterone from the animals own corpus luteum.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methanol

6.2 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

Do not store above 25°C. Protect from light. Store in a dry place.

6.5 Nature and composition of immediate packaging

The Morlam sponges are packed in plastic bags, sealed with a clip and stored in a white cardboard box. The white cardboard boxes contain 2 x 50 sponges per bag. They are stored in an outer corrugated brown cardboard box which holds 1000 sponges. The applicator consists of a rod and a tube.

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

After removal, the used sponges should be burnt, or disposed of in the proper manner.
Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Laboratorios Ovejero S.A.,
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24192
Leon
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10396/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal of the last authorisation: 30th September 2007

10 DATE OF REVISION OF THE TEXT

March 2016