



MELOVINE®

Product information

CONTENTS

1 	Name of the veterinary medicinal product	3
2 	Qualitative and quantitative composition	3
3 	Pharmaceutical form	3
4 	Clinical particulars	3
5 	Pharmacological properties	6
6 	Pharmaceutical particulars	6

These pages are general information pages. No guarantee is given as to the completeness of the information contained or its compliance with national regulatory requirements. Users should consult the local site of their countries to obtain information that complies with applicable national regulations.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovine.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One coated implant contains:

Active substance:

Melatonin 18 mg

Excipients:

Quinoline yellow lake (E104) 0.04 mg

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

3. PHARMACEUTICAL FORM

Implant.

Yellow cylindrical implant.

4. CLINICAL PARTICULARS

4.1 | Target species

Sheep (ewe and male), goats (adult female).

4.2 | Indications for use, specifying the target species

Sheep (sexually mature ewes and shearlings):

To improve reproductive performance and induce the sexual activity in advance of the natural breeding season.

Sheep (rams):

To induce the sexual activity in advance of the natural breeding season.

Goats (sexually mature does):

Increase fertility and fecundity of goats in seasonal anoestrus period.

4.3 | Contraindications

Do not use on sexually immature female.

Do not use in case of hypersensitivity to the active ingredient or any of the excipients.

4.4 | Special warnings for each target species

The veterinary medicinal product is not intended for the treatment of reproductive problems associated with a disease, poor health conditions, dietary imbalances or any other cause, therefore, the use of the veterinary medicinal product in animals with the afore mentioned disorders is not recommended.

In goats, apply to females that have had at least one kidding, and have passed at least 5 months since it.

4.5 | Special precautions for use

- i : Special precautions for use in animals**
 - : The veterinary medicinal product is sterile. Carefully tear along the perforations to open each part of the blister as needed.
 - : Avoid the deterioration of the implants.
 - : For implantation, use only needles in good condition.
 - : Respect the usual hygiene precautions during implantation.

- ii : 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 case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
 - : Wash hands after use.

- iii : Other precautions**
 - : None.

4.6 | Adverse reactions (frequency and seriousness)

Not known.

4.7 | Use during pregnancy, lactation or lay

Laboratory study in mouse has not produced any evidence of a teratogenic effect.

In case of accidental use of the veterinary medicinal product in pregnant females, no adverse effect is anticipated.

Use in lactating females is possible, although it may not give optimal results.

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

None known.

4.9 | Amounts to be administered and administration route

Use the special implanter to administer subcutaneously at the base of the ear one implant per female and three implants per male.

Rest on the trigger of the implanter to release an implant. Releasing the trigger moves the cartridge forward one step in the implanter guide to prepare the next implant for administration.

Sheep:Treatment scheme with natural mating (without oestrus synchronisation):

Day 1: 30 weeks before the expected lambing date.

Separate females from breeding rams when they are not separated.

Administer three implants to the rams.

Day 7: administer one implant per female.

Day 42: 30 to 40 days after the implantation of the females, introduce the breeding rams. It is possible that sexual activity only begins after 14 to 21 days. The introduction of vasectomized rams during the first 14 days allows lambing concentration. The maximum sexual activity occurs between 25 to 35 days after the introduction of the ram(s). The time interval between the administration of the implant and the introduction of the rams should be no less than 30 days or more than 40 days.

Treatment scheme with artificial insemination or natural mating (with oestrus synchronisation):

Treatment with this veterinary medicinal product can be combined with oestrus synchronization treatment using fluorogestone acetate-based vaginal sponges and equine Chorionic Gonadotrophin (eCG) administration according to the following scheme:

Day 1: place an implant of this veterinary medicine.

Day 18 to 28: place a fluorogestone acetate-based sponge.

Day 30 to 40: remove the sponge and administer eCG intramuscularly (according to the recommended use schemes for fluorogestone acetate-based medicines and eCG).

Artificial insemination should take place 55+/- 1 hours after removing the sponge.

Goats:Treatment scheme with natural mating (without oestrus synchronization):

Day 1: 30 weeks before the expected date of kidding date.

Separate the females from the males when they are not separated.

Administer one implant per female.

Day 45: introduce the males.

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

No special measure is required.

In any event, overdose is highly unlikely.

4.11 | Withdrawal period(s)

Meat and offal: zero days.

Milk: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Melatonin receptor agonists (melatonin).

ATCvet code: QN05CH01

5.1 | Pharmacodynamic properties

Melatonin is a hormone naturally secreted by the adenohypophysis. Melatonin is the internal hormonal mechanism that informs the body of variations in the length of days throughout the year. Its secretion takes place at night (in the absence of light).

In small ruminants, the progressive increase in the length of the nights after the summer solstice (June) causes an increase in melatonin secretion, which leads to the induction of sexual activity.

The veterinary medicinal product simulates this phenomenon; each implant progressively releases melatonin at rates comparable to those observed during the endogenous nocturnal secretion phase. Its application, under the recommended conditions of use, stimulates the early onset of sexual activity and improves the reproductive efficiency of females treated before the natural sexual season, reducing the number of non-pregnant females and increasing the number of lambs born per female.

5.2 | Pharmacokinetic particulars

Melatonin shows good absorption after subcutaneous administration. The absolute bioavailability of melatonin released by the implant is 81% based on published results on the pharmacokinetics of melatonin after intravenous administration in sheep.

Four days after implant placement, plasma concentrations are regular and higher than standard daytime levels, maintaining up to four months.

Melatonin is metabolized in the liver to form 6-hydroxymelatonin, which is conjugated with sulfate or glucuronic acid and is almost exclusively eliminated in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 | List of excipients

Quinoline yellow aluminium lake (E104)

Ethyl cellulose

Vegetable oil hydrogenated

Dibutyl Phtalate

6.2 | Incompatibilities

None.

6.3 | Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

6.4 | Special precautions for storage

None.

6.5 | Nature and composition of immediate packaging

Low density polyethylene cartridges with 25 implants per blister (PVC) closed by an aluminium foil. Two blister trays (50 implants) are surrounded by a cardboard carton.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.