1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ovimel 18 mg implantation tablets for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Melatonin 18.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Tablet core	
Quinoline yellow (E104)	0.01 mg
Ethylcellulose	-
Povidone	-
Magnesium stearate	-
Hydrogenated vegetable oil	-
Tablet coating	
Ethylcellulose	-
Dibutyl sebacate	-

Film-coated implantation tablets yellowish to ochre colour

3. CLINICAL INFORMATION

3.1 Target species

Sheep (sexually mature ewes)

3.2 Indications for use for each target species

To improve reproductive performance in sheep intended to be mated early in the season, before the usual peak in reproductive activity.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

- This veterinary medicinal product will not synchronise oestrus.
- This veterinary medicinal product should only be used in sexually mature ewes (having lambed at least once).
- The reproductive performance in females treated with this veterinary medicinal product to advance the breeding season, is not superior to that obtained in the natural reproductive season.

- This veterinary medicinal product is intended only to overcome the effects of seasonality on the reproductive cycle. In the presence of other reproductive problems associated with pathological processes (abortions, mastitis), poor sanitary conditions, nutritional imbalances or any other cause, it is not advisable to use this veterinary medicinal product and veterinary advice should be sought.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product is sterile. Carefully tear along the perforations to open each part of the blister when needed.
Avoid damaging implants. Use only sharp, undamaged needles.
Respect the usual conditions of hygiene during implantation.
Unless single-use needles are used for the administration of the implant, there is a risk of transmission of infectious diseases between treated animals.

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

Administer the veterinary medicinal product with caution 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.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation, although it will not give optimal results as this veterinary medicinal product is not intended for use during pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous use

Dose: One implant per sexually mature ewe.

Administer at the base of the ear using the special gun provided. Introduce the needle in the subcutaneous area at the base of the ear. Press the trigger of the gun to release an implant. When the trigger is released, the gun automatically reloads.

Do not administer if sheep are wet or dirty.

The timing of implant application must be adapted to the photoperiod of the region and the seasonality of the animals, depending upon the breeds and production systems.

SHEEP (sexually mature ewe): Treatment regime without synchronization and with natural mating.

- Day 1 (30 weeks prior to intended lambing date):
- Isolate females from all males, if they are not normally separated.

- Day 7:
- Administer a subcutaneous implant at the base of the female's ear (with the special gun).

- Day 37-47 (between 30-40 days after implant administration):
- Introduce the rams. Sexual activity may not start immediately. A delay of 14 to 21 days should be expected before mating activity commences. Vasectomised rams may be used for the first 14 days to ensure a more compact lambing period. Maximum sexual activity occurs between 25 and 35 days after the introduction of the males.

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

Overdose is highly unlikely given the characteristics of the veterinary medicinal product and its route of administration. No special actions required.

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: Zero days.
Milk: Zero hours.

It is essential that the veterinary medicinal product is only administered subcutaneously at the base of ear.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

ATC vet code: QN05CH01.

4.2 Pharmacodynamics

Melatonin, the active substance of this veterinary medicinal product, is a hormone naturally secreted by the anterior pituitary gland. Melatonin signals photoperiodic change to the body, ie. variations in the day length throughout the year. Its secretion takes place during the night hours of darkness.

As day length decreases, melatonin secretion increases and triggers increased reproductive activity, thus producing a natural peak in breeding performance in the autumn.

This veterinary medicinal product simulates the phenomenon; each implantation tablet gradually releases melatonin for 3 to 4 months at rates comparable to those observed during the endogenous nocturnal secretion phase.

4.3 Pharmacokinetics

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

Fourteen days after the placement of the implant, the plasma concentrations are stable and higher than the standard diurnal levels, remaining up to three months.

Melatonin is metabolized in the liver to form 6-hydroxymelatonin that is conjugated with sulfate or glucuronic acid and excreted almost exclusively by urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30

months. Shelf life after first opening the immediate packaging: use

immediately.

The remaining implantation tablets must be discarded after first opening the cartridge.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

One box with 2 PVC/Alu Blisters containing one low-density polyethylene multi-shot tag cartridge with 25 implantation tablets each.

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

VETPHARMA ANIMAL HEALTH, S.L.

7. MARKETING AUTHORISATION NUMBER

VPA10516/027/001

8. DATE OF FIRST AUTHORISATION

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

30/04/2025

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).