SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regulin® 18 mg implant

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

mg per implant

Active ingredient:	Melatonin	18.00
Other ingredients:	Quinoline yellow lake (E104)	0.04

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Implant.
Yellow cylindrical implant.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep (ewes)

4.2 Indications for use

To improve the reproductive performance of pure bred and cross bred lowland sheep which are to be mated early in the season before the usual peak of reproductive activity.

When used as directed, it stimulates the early onset of natural reproductive activity giving improved reproductive performance of flocks mated early in the season. The product is recommended for use in Suffolk and Suffolk-cross type flocks intended to start lambing between early December and mid-January and in the Mule and half-bred flocks starting lambing between late December and mid-February.

4.3 Contra-indications

Only use in adult ewes and shearlings
Do not use at times other than those recommended
Use by subcutaneous implantation at the base of the ear only
Not effective on sexually immature animals

4.4 Special warnings for each target species

Regulin® only overcomes the effects of seasonality. If there are any other adverse influences on reproduction present within a flock, the full benefit of Regulin treatment may be reduced or even eliminated. Aspects of implantation related to animal welfare and more intensive husbandry practices should be discussed with your veterinary surgeon prior to use.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i. Special precautions for use in animals

Avoid damaging implants. Use only sharp undamaged needles. Needles should be from gamma irradiated packs only. Replace the needle after each batch of 25 sheep to overcome blunting. Regulin will not synchronise oestrus.

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

Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Use in ewes suckling lambs at foot may not give optimum results. The product will be safe to use in pregnant ewes but obviously will not be effective.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Dose:
One implant per ewe by subcutaneous administration at the base of the ear.

Administration:
Use the implanter to administer one implant near the base of the ear.

In Suffolk and Suffolk-cross types, the implant should be used from mid-May to late June for ram introduction in late June and July. In Mule and half-bred flocks it should be administered from early June to July for ram introduction from mid-July to late August.

Do not use at times other than those recommended. Do not administer if sheep are wet or dirty.

Treatment regime:
Day 1 (30 weeks before intended start of lambing).

As the presence of any ram (and also male goats) will interfere with the ovulatory process, isolate ewes from all males. The ewes should be out of sight, sound and smell. Separating males into the next field from females is not adequate.

Day 7:
Implant ewes at the base of the ear. Do not administer if sheep are wet or dirty. Ewes must remain isolated from male sheep and goats.

Day 42 (35 days after implantation):
The period between implanting and introduction of the males must be not less than 30 days and no more than 40 days. Introduce rams, but expect a delay of 14-21 days before mating activity commences. Vasectomised rams may be used for the first 14 days to ensure a more compact lambing period. The peak of mating activity will occur 25-35 days after introduction of the rams.

4.10 Overdose (Symptoms, emergency procedures, antidotes)

No special actions required. In any event, overdose is highly unlikely

4.11 Withdrawal periods

Meat: Zero days
Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Regulin® implants contain melatonin, a natural secretion of the pineal gland. Melatonin is the day length messenger by which all animals recognise different seasons. The pineal gland only produces melatonin during hours of darkness. As days shorten the amount of melatonin secreted increases and this signals the reproductive system to increase activity, producing a natural peak in breeding performance in the autumn. Regulin works by mimicking this effect: each implant slowly releases melatonin over an extended period.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quinoline yellow aluminium lake (E104)
Ethyl cellulose (E462)
Vegetable oil hydrogenated
Dibutyl Phtalate

6.2 Major incompatibilities

None known

6.3 Shelf-life

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

6.4 Special precautions for storage

The product is sterile. Only open each blister section when required. To maintain sterility, opened product must be discarded at the end of the working day.
Keep blister trays in outer carton.

6.5 Nature and contents of container

25 yellow cylindrical implants are contained in separate wells of a polythene cartridge, designed to fit a manually operated implanter gun. Cartridges are housed in preformed UPVC blister trays sealed with foil. Two blister trays (50 implants) are surrounded by a cardboard carton.

6.6 Special precautions for the disposal of unused medicinal product or waste materials if any

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

CEVA Animal Health Ltd
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8. MARKETING AUTHORISATION NUMBER

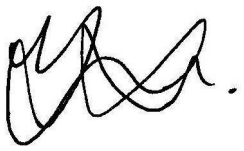
Vm 15052/4011

9. DATE OF FIRST AUTHORISATION

01 January 1993

10. DATE OF REVISION OF THE TEXT

October 2022



Approved: 03 October 2022