PARTICULARS TO APPEAR ON THE OUTER BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regulin® 18 mg implant

Melatonin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each implant contains 18 mg melatonin.

3. PHARMACEUTICAL FORM

Implant

4. PACKAGE SIZE

50 implants

5. TARGET SPECIES

Ewes

6. INDICATION(S)

For improved reproductive performance of sheep which are to be mated early in the season.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer one implant to ewes subcutaneously at the base of the ear 30 to 40 days prior to introduction of rams.
Use the Regulin implanter gun.
Keep ewes isolated from male sheep or goats for at least six weeks prior to mating.
See enclosed leaflet for complete directions for use.

8. WITHDRAWAL PERIOD

Meat and milk: 0 days

9. SPECIAL WARNING(S), IF NECESSARY

Use by subcutaneous implantation at the base of the ear only. Avoid damaging implants. Use only sharp undamaged needles. Needles should be from gamma irradiated packs only. Do not administer if sheep are wet or dirty. Regulin does not synchronise oestrus. Only use in adult ewes or shearlings. Regulin will not be effective on sexually immature animals. Use of Regulin in ewes suckling lambs at foot may not give optimum results. Do not use at times other than those

recommended. Variable results may be seen following use of the product, associated with the management systems involved.
Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.

10. EXPIRY DATE

Exp date

11. SPECIAL STORAGE CONDITIONS

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 blisters in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the enclosed package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS
To be supplied only on veterinary prescription.

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 14966/3016

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON BLISTER TRAYS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regulin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

18mg implant , melatonin

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

25 implants by blister tray

25 Regulin implants each containing 18 mg melatonin

4. ROUTE(S) OF ADMINISTRATION

For subcutaneous implantation at the base of the ear only.

5. WITHDRAWAL PERIOD

Read package leaflet.

6. WARNINGS

This product is sterile. Only open this blister section when required.

To maintain sterility opened product must be discarded at the end of the working day.

Keep out of reach and sight of children.

For further information and user warnings please read the package leaflet.

7. BATCH NUMBER

Batch nº:

8. EXPIRY DATE

Exp:

9. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS
To be supplied only on veterinary prescription.

For animal treatment only.

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

11. MARKETING AUTHORISATION NUMBER(S)

Vm 14966/3016

PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Manufacturer responsible for batch release: Ceva Santé Animale, 10 avenue de la Ballastière, 33 500 Libourne, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regulin® 18 mg implant

Melatonin

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each implant contains 18 mg melatonin.

4. INDICATION(S)

For improved reproductive performance of sheep which are to be mated early in the season

Regulin is intended for use on pure bred and crossbred lowland sheep breeds to improve reproductive performance when mated early in the season. Aspects of implantation related to animal welfare and more intensive animal husbandry practices should be discussed with your veterinary surgeon prior to use.

5. CONTRAINDICATIONS

Use by subcutaneous implantation at the base of the ear only. Avoid damaging implants. Use only sharp undamaged needles. Needles should be from gamma irradiated packs only. Do not administer if sheep are wet or dirty. Regulin does not synchronise oestrus. Only use in adult ewes or shearlings. Regulin will not be effective on sexually immature animals. Use of Regulin in ewes suckling lambs at foot may not give optimum results. Do not use at times other than those recommended. Variable results may be seen following use of the product, associated with the management systems involved.

IMPORTANT

Use of Regulin cannot increase performance beyond the level achievable naturally form mating at the seasonal peak. Regulin will not compensate for fertility problems associated with husbandry, disease, nutrition or other factors. Regulin only overcomes the effects of seasonality and use in pregnant ewes with lamb at foot will not be effective.

If there are any other adverse influences on reproduction present within the flock the full benefit of Regulin treatment may be reduced or even eliminated.

6. ADVERSE REACTIONS

None

7. TARGET SPECIES

Sheep (ewes)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

One implant per ewe by subcutaneous implantation to be administered 30-40 days before ram introduction.

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; 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.

9. ADVICE ON CORRECT ADMINISTRATION

Use the Regulin implanter to administer subcutaneously near the base of the ear (ie implant under a pinch of skin behind the ear). Full directions are included with the Regulin applicator gun. For ease of implantation, the needle should be replaced after

each batch of 25 sheep to overcome blunting. Normal hygienic precautions should be observed during implantation. Needles should be from gamma irradiated packs only. Do not administer id sheep are wet or dirty.

TIMING

It is expected that mating and therefore lambing will occur over about 30 days with an early peak. Regulin 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.

Do not use Regulin at times other than recommended and only use in adult ewes and shearlings.

10. WITHDRAWAL PERIOD(S)

Meat: Zero days
Milk: Zero hours

11. SPECIAL STORAGE PRECAUTIONS

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 blisters in outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Avoid damaging implants. Use only sharp undamaged needles. Needles should be from gamma irradiated packs only. Do not administer if sheep are wet or dirty.

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. Variable results may be seen following use of the product, associated with the management systems involved. 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. Regulin does not synronise oestrus.

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.

For Animal Treatment Only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED 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.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Keep out of reach the reach and sight of children

Vm 14966/3016

POM-VPS
To be supplied only on veterinary prescription.

Introduction
As sheep are seasonal breeders, though the degree of seasonality exhibited varies between breeds. The peak of reproductive activity for all sheep occurs in autumn. During this peak, a high proportion of flock is ovulating and showing heat, and the highest ovulation rates are achieved. Females mated at this time will perform at optimum level. When early lambing is required (eg December-January), it is necessary to introduce the males in July/August when females are normally anoestrus. This would normally lead to poorer results, with higher incidence on non-pregnant females, a lower lambing percentage, and an extended lambing period. Use of this product is likely to modify this situation.

What is Regulin?
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 nights lengthen the duration melatonin secreted increases and this signals the reproductive system to increase activity, Peak reproductive activity is reached in autumn. Regulin works by mimicking this effect: each implant slowly releases melatonin over an extended period. When used as directed, it stimulates the early onset of natural reproductive activity giving improved reproductive performance of flocks mated early in the season.
Regulin treatment of female sheep mated early in the season results in:

Fewer non-pregnant females
More lambs born per female exposed to the ram
A more concentrated mating, and hence lambing pattern
Regulin will not improve performance beyond the natural peak obtainable from a natural mating. The nature and extent of response will depend upon the time of treatment relative to the start of the breeding season. Flocks may show some variation in response to treatment. Regulin will not synchronize oestrus.

Gavin Hall
Approved: 30 September 2025