

ANNEX III
LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE: COMBINED LABEL AND PACKAGE LEAFLET

Laminated polypropylene sachet for 10 strips

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calistrip Biox 6.44 g bee-hive strip for honey bees.

2. COMPOSITION

Each 50.74 g strip contains:

Active substance:

Oxalic acid dihydrate.....6.44 g
(Equivalent to 4.6 g of oxalic acid)

Whitish or yellowish solid mixture incorporated in a rectangular strip with two tabs and two marked fold lines.

3. PACKAGE SIZE

2 strips
10 strips

4. TARGET SPECIES

Honey bees (*Apis mellifera*)

5. INDICATIONS FOR USE

Indications for use

Treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*)

6. CONTRAINDICATIONS

Contraindications

None

7. SPECIAL WARNINGS

Special warnings

Special warnings:

For best efficacy, the veterinary medicinal product should be used only when brood is absent or at its lowest levels. Oxalic acid does not penetrate the wax, so it does not kill the mites inside the capped brood cells and therefore the presence of brood can considerably reduce the effectiveness of the veterinary medicinal product. Level of brood and climatic conditions must be considered prior to product application. The mode of action of the product is only by direct contact (by contact of adult bees with oxalic acid in the strip and by bee-to bee contact). As consequence, the product should be applied when the bees are still active, i.e. before the bees form a winter cluster, the exact timing of which can vary between climatic zones.

Despite proper treatment, seriously damaged colonies may not survive due to prior effects of Varroa infestation. The efficacy may vary between colonies due to the conditions of use (temperature, reinfestations etc.). No efficacy or safety clinical data were provided for other conditions than Autumn in Southern Europe.

The veterinary medicinal product should be used as a treatment within an Integrated Varroa Management program with mite drop monitored regularly. When possible, rotate the use of this veterinary medicinal product with another approved varroacide with a different mode of action to decrease the potential for Varroa mites to develop resistance.

The use of a bottom net with a metal mesh of approximately 3x3 mm is a recommended practice in a comprehensive varroosis control program that includes the use of the veterinary medicinal product.

Special precautions for safe use in the target species:

All colonies in the same apiary must be treated simultaneously to avoid reinfestation.

Do not re-use the strips.

Bee colonies should be monitored routinely for the level of varroa mite infestation during treatment and also for a period thereafter.

The effect of veterinary medicinal product has not been studied in presence of super, for this reason it cannot be used in the hive if the honey supers are installed.

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

This veterinary medicinal product could have irritating effects on the skin, eyes and mucous membranes. Avoid contact with skin, eyes or mouth.

Wear the usual beekeeping protective clothing and gloves when handling and administering the product.

In the case of accidental skin contact, wash thoroughly with soap and water.

In case of accidental eye contact, flush the eyes with plenty of clean, running water.

If skin/eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Interactions with other medicinal products and other forms of interaction:

Do not use simultaneously with other acaricides.

Overdose:

No adverse events were observed when 2 strips/hive containing 10 g oxalic acid dihydrate each one was administered for a period of 6 weeks nor 4 strips/hive (administered as two consecutive treatments of 3 weeks using 2 strips/hive/treatment) containing 10g oxalic acid dihydrate each one administered in two consecutive treatments of 3 weeks (2 strips/hive/treatment).

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In-hive use.

Use two strips per hive (i.e. 12.88 g of oxalic acid dihydrate per hive), hang each strip between two frames of honeycomb food stores. Place the strips between frames where the bees exhibit the greatest mobility. Hang the strips in such a way as to provide bees with free access to both sides, whilst maintaining bee space. The strips have two-fold lines so that the length of the strip can be adjusted according to the characteristics of each type of hive. Through the fold lines, the strips can be used in hives that requires long strips (~30 cm) and also in hives that require short strips (~25 cm).

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Strips must be removed after 6 weeks.

The strips should not be cut.

The product should be used when the amount of brood is low relative to peak levels. In addition, the product should be applied when the bees are still active, i.e. before the bees form a winter cluster, the exact timing of which can vary between climatic zones. Therefore, levels of brood and climatic conditions must be considered prior to product application.

Do not use the veterinary medicinal product if you notice visible signs of deterioration.

11. WITHDRAWAL PERIODS

Withdrawal periods

Honey: Zero days.

Do not use during honey flow. Do not extract honey from the brood chamber.

Do not harvest honey during the 6-week treatment period.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the sachet after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

[To be completed nationally]

Package sizes

Sachet containing 2 bee-hive strips.

Sachet containing 10 bee-hive strips.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised.

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

[To be completed nationally]

Manufacturer responsible for batch release:

Laboratorios Calier S.A.

C/ Barcelones 26

Poligono Industrial El Ramassa

Les Franqueses del Valles

Barcelona

08520 Spain

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

[To be completed nationally]

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 6 months.

Once opened used by ...

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Laminated polypropylene sachet for 2 strips

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calistrip Biox 6.44 g bee-hive strip for honey bees

2. STATEMENT OF ACTIVE SUBSTANCES

Each 50.74 g strip contains:

Active substance:

Oxalic acid dihydrate.....6.44 g

(Equivalent to 4.6 g of oxalic acid)

3. PACKAGE SIZE

2 bee-hive strips

10 bee-hive strips

4. TARGET SPECIES

Honey bees (*Apis mellifera*)

5. INDICATIONS

Treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*)

6. ROUTES OF ADMINISTRATION

In-hive use.

7. WITHDRAWAL PERIODS**Withdrawal period:**

Honey: Zero days.

Do not use during honey flow. Do not extract honey from the brood chamber.

Do not harvest honey during the 6-week treatment period.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months

9. SPECIAL STORAGE PRECAUTIONS**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
--

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
--

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier S.A.

14. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

15. BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

(Laminated polypropylene sachet for 2 strips)

1. Name of the veterinary medicinal product

Calistrip Biox 6.44 g bee-hive strip for honey bees.

2. Composition

Each 50.74 g strip contains:

Active substance:

Oxalic acid dihydrate.....6.44 g
(Equivalent to 4.6 g of oxalic acid)

Whitish or yellowish solid mixture incorporated in a rectangular strip with two tabs and two marked fold lines.

3. Target species

Honey bees (*Apis mellifera*).

4. Indications for use

Treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*).

5. Contraindications

None.

6. Special warnings

Special warnings:

For best efficacy, the veterinary medicinal product should be used only when brood is absent or at its lowest levels. Oxalic acid does not penetrate the wax, so it does not kill the mites inside the capped brood cells and therefore the presence of brood can considerably reduce the effectiveness of the veterinary medicinal product. Level of brood and climatic conditions must be considered prior to product application. The mode of action of the product is only by direct contact (by contact of adult bees with oxalic acid in the strip and by bee-to bee contact). As consequence, the product should be applied when the bees are still active, i.e. before the bees form a winter cluster, the exact timing of which can vary between climatic zones.

Despite proper treatment, seriously damaged colonies may not survive due to prior effects of Varroa infestation. The efficacy may vary between colonies due to the conditions of use (temperature, reinfestations etc.). No efficacy or safety clinical data were provided for other conditions than Autumn in Southern Europe.

The veterinary medicinal product should be used as a treatment within an Integrated Varroa Management program with mite drop monitored regularly. When possible, rotate the use of this

veterinary medicinal product with another approved varroacide with a different mode of action to decrease the potential for Varroa mites to develop resistance.

The use of a bottom net with a metal mesh of approximately 3x3 mm is a recommended practice in a comprehensive varroosis control program that includes the use of the veterinary medicinal product.

Special precautions for safe use in the target species:

All colonies in the same apiary must be treated simultaneously to avoid reinfestation.

Do not re-use the strips.

Bee colonies should be monitored routinely for the level of varroa mite infestation during treatment and also for a period thereafter.

The effect of the veterinary medicinal product has not been studied in presence of super, for this reason it cannot be used in the hive if the honey supers are installed.

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

The veterinary medicinal product could have irritating effects on the skin, eyes and mucous membranes. Avoid contact with skin, eyes or mouth.

Wear the usual beekeeping protective clothing and gloves when handling and administering the product.

In the case of accidental skin contact, wash thoroughly with soap and water.

In case of accidental eye contact, flush the eyes with plenty of clean, running water.

If skin/eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other acaricides.

Overdose:

No adverse events were observed when 2 strips/hive containing 10 g oxalic acid dihydrate each one was administered for a period of 6 weeks nor 4 strips/hive (administered as two consecutive treatments of 3 weeks using 2 strips/hive/treatment) containing 10g oxalic acid dihydrate each one administered in two consecutive treatments of 3 weeks (2 strips/hive/treatment).

Special restrictions for use and special conditions for use:

Not applicable.

7. Adverse events

None Known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

In-hive use.

Use two strips per hive (i.e. 12.88 g of oxalic acid dihydrate per hive), hang each strip between two frames of honeycomb food stores. Place the strips between frames where the bees exhibit the greatest mobility. Hang the strips in such a way as to provide bees with free access to both sides, whilst maintaining bee space. The strips have two-fold lines so that the length of the strip can be adjusted

according to the characteristics of each type of hive. Through the fold lines, the strips can be used in hives that requires long strips (~30 cm) and also in hives that require short strips (~25 cm).

9. Advice on correct administration

Strips must be removed after 6 weeks.

The strips should not be cut.

The product should be used when the amount of brood is low relative to peak levels. In addition, the product should be applied when the bees are still active, i.e. before the bees form a winter cluster, the exact timing of which can vary between climatic zones. Therefore, levels of brood and climatic conditions must be considered prior to product application.

Do not use the veterinary medicinal product if you notice visible signs of deterioration.

10. Withdrawal periods

Honey: Zero days.

Do not use during honey flow. Do not extract honey from the brood chamber.

Do not harvest honey during the 6-week treatment period.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the sachet label after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription

14. Marketing authorisation numbers and pack sizes

[To be completed nationally]

Package sizes:

Sachet containing 2 bee-hive strips.

Sachet containing 10 bee-hive strips.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

[To be completed nationally]

Manufacturer responsible for batch release:

Laboratorios Calier S.A.
C/ Barcelones 26
Poligono Industrial El Ramassa
Les Franqueses del Valles
Barcelona
08520 Spain

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

[To be completed nationally]

17. Other information