

ANNEX II

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Container Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectron
Spot-on Solution for Cattle and Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Deltamethrin 10 mg/ml

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

250 mL
500 mL
1 Litre
2.5 L

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

A topical application for the control of lice and flies on cattle; ticks, lice, keds and established blowfly strike on sheep and lice and ticks on lambs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD:

Cattle (meat) – 17 days
Cattle (milk) – zero hours
Sheep (meat) – 35 days

This product is not authorised for use in ewes producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY
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For external use only.

Shake well before use.

10. EXPIRY DATE

EXP: END MM/YYYY

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY
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13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-VPS

 To be supplied only on veterinary prescription

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorization Holder:

Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallaght
Dublin 24
Ireland

Distributed in the UK by:

Bimeda ®
Cross Vetpharm Group UK
Ltd. Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4024

17. MANUFACTURER'S BATCH NUMBER
--

Batch No.:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Container Carton 250ml/500ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectron
Spot-on Solution for Cattle and Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Deltamethrin 10 mg/ml

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

250 mL
500 mL

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

INDICATIONS

A topical application for the control of lice and flies on cattle; ticks, lice, keds and established blowfly strike on sheep and lice and ticks on lambs.

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD

Cattle (meat) – 17 days

Cattle (milk) – zero hours

Sheep (meat) – 35 days

The product is not authorised for use in ewes producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

SHAKE WELL BEFORE USE

FOR EXTERNAL USE ONLY

SPECIAL WARNINGS

Wear protective clothing including waterproof apron and boots and impervious gloves when either applying the product or handling recently treated animals.

Remove heavily contaminated clothing immediately and wash before use.

Wash splashes from skin immediately with soap and plenty of water.

Wash hands and exposed skin after handling this product and before meals.

In case of contact with eyes, rinse immediately with plenty of clean, running water and seek medical advice.

In case of accidental ingestion, wash out mouth immediately with plenty of water and seek medical advice.

Do not smoke, drink or eat while handling the product.

This product contains deltamethrin which may produce tingling, itchiness and blotchy redness on exposed skin. If you feel unwell after working with this product, consult your doctor and show this label.

Advice to medical practitioners: Advice on clinical management is available from the National Poisons Information Service.

Care should be taken to avoid inaccurate dosing, misadministration or too frequent and repeated use of ectoparasiticides from the same class over an extended period of time as these practices increase the risk of development of resistance and could ultimately result in ineffective therapy.

Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle and sheep, e.g. by using only a single treatment per year on the same pasture. The risk to aquatic ecosystems will be further reduced by preventing treated sheep from entering watercourses for one hour immediately after treatment.

10. EXPIRY DATE

EXP:

The product must be used within 3 months of opening the container.

Once opened use by

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container, away from food, drink and animal feeding stuffs.

The veterinary medicinal product does not require any special temperature storage conditions. Keep the container in the outer carton in order to protect from light.

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

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

FOR ANIMAL USE ONLY

POM-VPS To be supplied only on veterinary prescription

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER:

Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallaght
Dublin 24
Ireland

Distributed in the UK by:

Bimeda ®
Cross Vetpharm Group UK
Ltd. Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA,
United Kingdom

16. MARKETING AUTHORISATION NUMBER
--

Vm 50146/4024

17. MANUFACTURER'S BATCH NUMBER

Batch No.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Container Carton 1 Litre/2.5 Litres

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectron
Spot-on Solution for Cattle and Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Deltamethrin 10 mg/ml

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 Litre
2.5 Litres

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

INDICATIONS

A topical application for the control of lice and flies on cattle; ticks, lice, keds and established blowfly strike on sheep and lice and ticks on lambs.

On cattle: for the control of both sucking and biting lice, including *Damalinia bovis*, *Solenopotes capillatus*, *Linognathus vituli* and *Haematopinus eurysternus* on all ages of cattle including dairy cattle producing milk for human consumption. Also as an aid in the control of both biting and nuisance flies including *Haematobia irritans*, *Stomoxys calcitrans*, *Musca* species and *Hydrotaea irritans*.

On sheep: For the control of ticks *Ixodes ricinus* and of lice and keds and established blowfly strike.

On lambs: For the control of ticks *Ixodes ricinus* and lice *Bovicola ovis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

METHOD AND ROUTES OF ADMINISTRATION

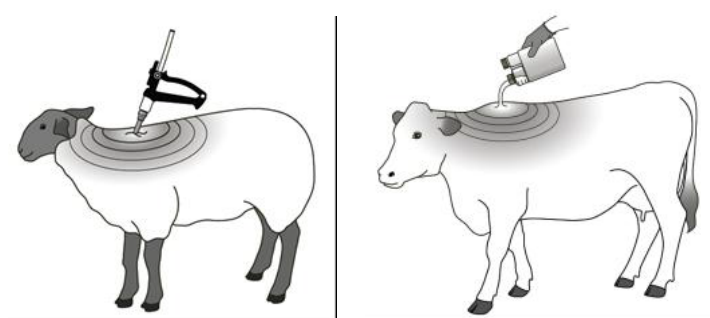
Dose:

Cattle: 10 ml

Sheep: 5ml

Lambs (under 10 kg bodyweight or 1 month of age): 2.5ml

Administration: Apply a single dose with the special dispenser pack or the Ectron Applicator on one spot on the mid-line of the back at the shoulders as directed on dispenser or applicator gun pack. For blowfly strike on sheep, see following specific indication directions.



Lice on cattle: One application will generally eradicate all lice. Complete clearance of all lice may take 4 - 5 weeks during which time lice hatch from the eggs and are killed. A very few lice may survive on a small minority of animals. Therefore, it may be necessary on rare occasions to re-treat an animal 6 - 8 week later.

Flies on cattle: To control biting and non-biting flies, frequency of treatment will depend on the numbers and species of flies present. Where horn-flies predominate, good control can be expected for 4 - 8 weeks. Treatment for fly control should not be repeated within four weeks.

Ticks on sheep: Application to the mid-point of the shoulders will provide useful control of ticks attaching to animals of all ages, for up to 6 weeks after treatment.

Keds and lice on sheep: Application to the mid-point of the shoulders of sheep in short or long fleece will reduce the incidence of a biting louse or ked infestation over a 4 - 6 week period after treatment.

N.B. For control of ticks, keds and lice on sheep, the fleece should be parted and Spot On applied to the skin of the animal.

When using the Ectron applicator application to the skin can be achieved by inserting the T bar to separate the fleece and penetrate down to the skin level before squeezing the applicator handle.

Established blowfly strike on sheep: Apply directly to the maggot infected area as soon as the fly strike is seen. One application will ensure blowfly larvae are killed

in a short time. In the case of more advanced strike lesions, clipping out of stained wool before treatment is advisable.

Lice and ticks on lambs: Application to the mid-point of the shoulders will provide useful control of ticks for up to 6 weeks after treatment, and will reduce the incidence of biting lice over a 4-6 week period after treatment.

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD

Cattle (meat) – 17 days
Cattle (milk) – zero hours
Sheep (meat) – 35 days

The product is not authorised for use in ewes producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

SHAKE WELL BEFORE USE

FOR EXTERNAL USE ONLY

SPECIAL WARNINGS

Wear protective clothing including waterproof apron and boots and impervious gloves when either applying the product or handling recently treated animals. Remove heavily contaminated clothing immediately and wash before use. Wash splashes from skin immediately with soap and plenty of water. Wash hands and exposed skin after handling this product and before meals. In case of contact with eyes, rinse immediately with plenty of clean, running water and seek medical advice. In case of accidental ingestion, wash out mouth immediately with plenty of water and seek medical advice. Do not smoke, drink or eat while handling the product.

This product contains deltamethrin which may produce tingling, itchiness and blotchy redness on exposed skin. If you feel unwell after working with this product, consult your doctor and show this label.

Advice to medical practitioners: Advice on clinical management is available from the National Poisons Information Service.

Care should be taken to avoid inaccurate dosing, misadministration or too frequent and repeated use of ectoparasiticides from the same class over an extended period of time as these practices increase the risk of development of resistance and could ultimately result in ineffective therapy.

Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle and sheep, e.g. by using only a single treatment per year on the same pasture. The risk to aquatic ecosystems will be further reduced by preventing treated sheep from entering watercourses for one hour immediately after treatment.

10. EXPIRY DATE

EXP:

The product must be used within 3 months of opening the container.

Once opened use by

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container, away from food, drink and animal feeding stuffs.

The veterinary medicinal product does not require any special temperature storage conditions. Keep the container in the outer carton in order to protect from light.

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

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

FOR ANIMAL USE ONLY

POM-VPS To be supplied only on veterinary prescription

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER:

Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallaght
Dublin 24
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Distributed in the UK by:

Bimeda ®
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Ltd. Unit 2, Bryn Cefni
Llangefni
Anglesey
LL77 7XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4024

17. MANUFACTURER'S BATCH NUMBER
--

Batch No.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Ectron 10 mg/ml Spot-on Solution for Cattle & Sheep

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

Marketing Authorisation Holder and Manufacturer Responsible for Batch Release:
Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectron 10 mg/ml Spot-on Solution for Cattle and Sheep

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

<u>Active Substance</u>	<u>mg/ml</u>
Deltamethrin	10.0

4. INDICATION(S)

As a topical application for the control of lice and flies on cattle; ticks, lice, keds and established blowfly strike on sheep and lice and ticks on lambs.

On cattle: for the control of both sucking and biting lice, including *Damalinia bovis*, *Solenopotes capillatus*, *Linognathus vituli* and *Haematopinus eurysternus* on all ages of cattle including dairy cattle producing milk for human consumption. Also as an aid in the control of both biting and nuisance flies including *Haematobia irritans*, *Stomoxys calcitrans*, *Musca* species and *Hydrotaea irritans*.

On sheep: For the control of ticks *Ixodes ricinus* and of lice and keds and established blowfly strike.

On lambs: For the control of ticks *Ixodes ricinus* and lice *Bovicola ovis*.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Minor signs of discomfort have been seen in some cattle during the 48 hours after treatment. This is of no long term detriment to the animal.

7. TARGET SPECIES

Cattle and Sheep.

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

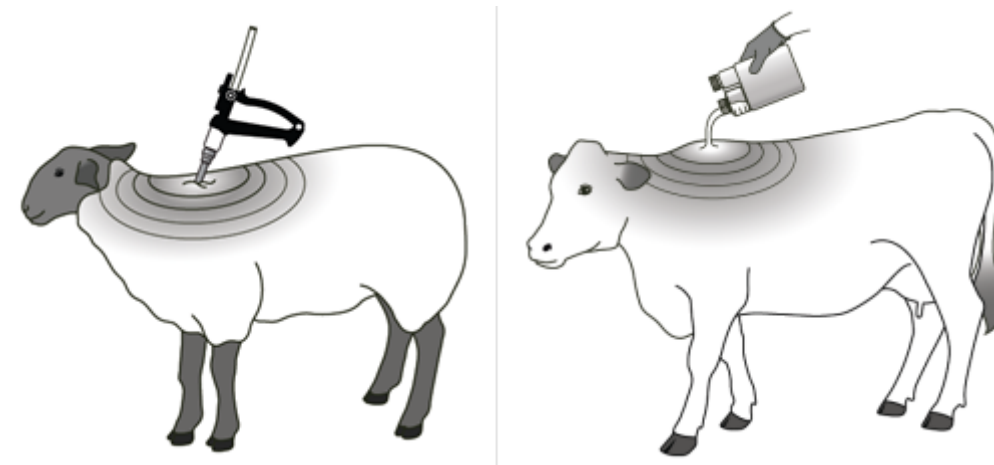
Dose:

Cattle: 10 ml

Sheep: 5ml

Lambs (under 10 kg bodyweight or 1 month of age): 2.5ml

Administration: Apply a single dose with the special dispenser pack or the Ectron Applicator on one spot on the mid-line of the back at the shoulders as directed on dispenser or applicator gun pack. For blowfly strike on sheep, see following specific indication directions.



Lice on cattle: One application will generally eradicate all lice. Complete clearance of all lice may take 4 - 5 weeks during which time lice hatch from the eggs and are killed. A very few lice may survive on a small minority of animals. Therefore, it may be necessary on rare occasions to re-treat an animal 6 - 8 weeks later.

Flies on cattle: To control biting and non-biting flies, frequency of treatment will depend on the numbers and species of flies present. Where horn-flies predominate, good control can be expected for 4 - 8 weeks. Treatment for fly control should not be repeated within four weeks.

Ticks on sheep: Application to the mid-point of the shoulders will provide useful control of ticks attaching to animals of all ages, for up to 6 weeks after treatment.

Keds and lice on sheep: Application to the mid-point of the shoulders of sheep in short or long fleece will reduce the incidence of a biting louse or ked infestation over a 4 - 6 week period after treatment.

N.B. For control of ticks, keds and lice on sheep, the fleece should be parted and Spot On applied to the skin of the animal.

When using the Ectron applicator application to the skin can be achieved by inserting the T bar to separate the fleece and penetrate down to the skin level before squeezing the applicator handle.

Established blowfly strike on sheep: Apply directly to the maggot infected area as soon as the fly strike is seen. One application will ensure blowfly larvae are killed in a short time. In the case of more advanced strike lesions, clipping out of stained wool before treatment is advisable.

Lice and ticks on lambs: Application to the mid-point of the shoulders will provide useful control of ticks for up to 6 weeks after treatment, and will reduce the incidence of biting lice over a 4-6 week period after treatment.

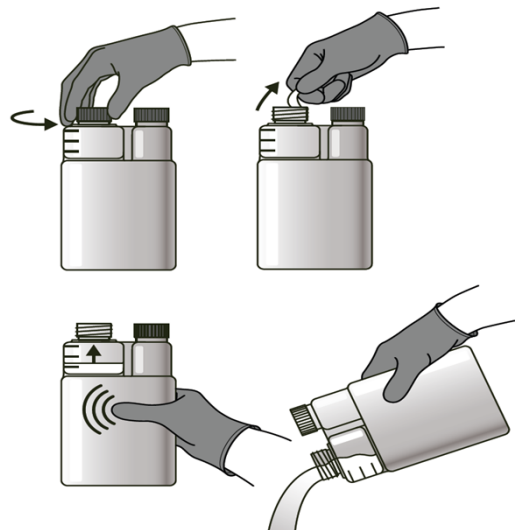
9. ADVICE ON CORRECT ADMINISTRATION

The product should be applied using an appropriate application device:

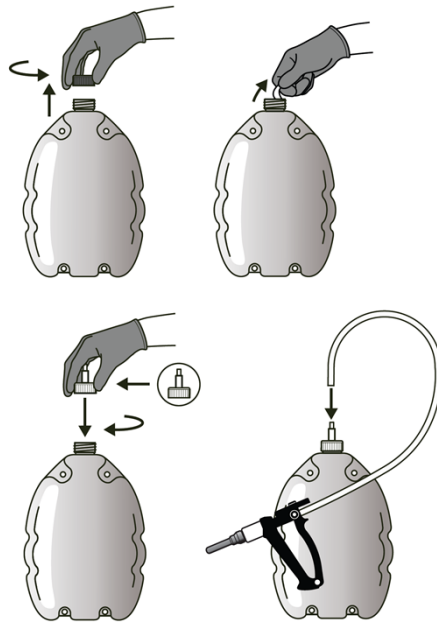
- For the 250ml and 500ml presentations a graduated chamber attached to the container is used.
- For the 1 litre and 2.5 litre presentations it is recommended to use an appropriate applicator.

The recommended use of the application devices is illustrated below.

1. Use of the graduated chamber on the 250ml and 500 ml containers:



2. Attaching the 1 and 2.5 litre containers to the recommended applicator:



Shake well before use.

10. WITHDRAWAL PERIOD

Cattle (meat) – 17 days
Cattle (milk) – zero hours
Sheep (meat) – 35 days

This product is not authorised for use in ewes producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

The veterinary medicinal product does not require any special temperature storage conditions. Keep the container in the outer carton in order to protect from light.

Store in tightly closed original container away from food, drink and animal feeding stuffs.

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

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton.

12. SPECIAL WARNING(S)

Special Precautions For Use

i) Special precautions for use in animals

Care should be taken to avoid inaccurate dosing, misadministration or too frequent and repeated use of ectoparasiticides from the same class over an extended period of time as these practices increase the risk of development of resistance and could ultimately result in ineffective therapy.

For external use only.

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

Wear protective clothing including waterproof apron and boots and impervious gloves when either applying the product or handling recently treated animals.

Remove heavily contaminated clothing immediately and wash before use.

Wash splashes from skin immediately with soap and plenty of water.

Wash hands and exposed skin after handling this product and before meals.

In case of contact with eyes, rinse immediately with plenty of clean, running water and seek medical advice.

In case of accidental ingestion, wash out mouth immediately with plenty of water and seek medical advice.

Do not smoke, drink or eat while handling the product.

This product contains deltamethrin which may produce tingling, itchiness and blotchy redness on exposed skin. If you feel unwell after working with this product, consult your doctor and show this label.

Advice to medical practitioners: Advice on clinical management is available from the National Poisons Information Service.

iii) Other precautions and environmental properties

Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees, is persistent in soils and may accumulate in sediments.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle and sheep, e.g. by using only a single treatment per year on the same pasture. The risk to aquatic ecosystems will be further reduced by preventing treated sheep from entering watercourses for one hour immediately after treatment.

Deltamethrin has the potential to adversely affect non-target organisms, both in water and in dung. Following treatment, excretion of potentially toxic levels of deltamethrin may take place over a period of 2 to 4 weeks. Faeces containing deltamethrin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

Use during pregnancy and lactation:

No special precautions are recommended.

Overdose:

There are no specific recommendations in the case of overdosage.

Interaction with other medicinal products and other forms of interaction:

Do not mix any other insecticide or acaricide with Ectron Spot-on Solution.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

15. OTHER INFORMATION

Vm 50146/4024

Available pack sizes: 250ml, 500 ml, 1 litre, 2.5 litres
Not all pack sizes may be marketed.

For animal treatment only.

For external use only.

POM-VPS

To be supplied only on veterinary prescription.

Approved: 24 July 2019

