

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGING

1 L - label and carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml Pour-on Solution for Sheep
Cypermethrin tech. (cis:trans / 80:20)

2. STATEMENT OF ACTIVE SUBSTANCES

Containing 12.5 mg/ml cypermethrin tech. (cis:trans / 80:20)
Contains Green S Dye (E142).

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZES

1 L

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

Ectofly is for the prevention and treatment of blowfly strike on sheep. Also used for the treatment and control of headflies, and treatment of tick infestation and biting lice on sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-On Solution

Read the package leaflet before use.
Shake well before use

The product must be applied only with a recommended applicator gun as the product may have a detrimental effect on certain components of standard applicator guns.

Full operating and maintenance instructions, including details on the use of nozzles, are supplied with each Pour-On Gun. To ensure accurate dosage of the product, maintain gun carefully.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

On completion of each treatment cycle of the product and before the dosing gun is stored, immediately expel any remaining product in the dosing gun.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 8 days.

Milk: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

This product contains a dye to aid in the identification of treated animals.

OPERATOR WARNINGS:

- This product is harmful if swallowed and may cause skin, eye or respiratory irritation. This product may also cause hypersensitivity reactions.
- Avoid skin and/or eye contact.
- Avoid children from getting access to the product or treated animals.
- Use in a well-ventilated area and avoid inhaling the vapour.
- Wear eye protection, protective clothing, rubber gloves and boots when applying the product and handling the animal until the product has dried.
- Wear a disposable face-mask when applying as a fan-spray for the prevention of blowfly-strike.
- Make sure when attaching the recommended applicator gun onto the container that the coiled retainer is secured onto the cap and the applicator.
- Wash splashes from skin and eyes immediately with plenty of clean water. If irritation persists seek medical advice immediately and show the package leaflet to the physician.
- Remove contaminated clothing immediately and wash exposed skin with plenty of clean water.
- Do not eat, drink or smoke whilst using the product. Wash hands immediately after use.
- In case of accidental ingestion or mouth contact, immediately rinse the mouth with plenty of water and seek medical advice.

OTHER PRECAUTIONS:

Cypermethrin is moderately persistent and non-mobile in soil. It is extremely toxic to aquatic invertebrates. Cypermethrin is toxic to dung insects and to honey bees.

Cypermethrin is extremely toxic to aquatic and dung organisms. As a precautionary measure sheep must be kept away from watercourses for at least 12 hours following treatment. Given the risks to the environment the use of the product should be limited to one treatment per year per pasture.

Long term effects on dung insects caused by continuous or repeated use of pyrethroid ectoparasiticides cannot be excluded. Therefore repeated treatment of animals on the same pasture with a pyrethroid-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

10. EXPIRY DATE

EXP {*month/year*}

Once broached use by

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

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container in a safe place.

Do not store above 25°C.

Protect from direct sunlight.

Store away from food, drink and animal feedstuffs.

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

EXTREMELY DANGEROUS to aquatic invertebrates. Do not contaminate ponds, waterways or ditches with the product or empty container.

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

Disposal: read package leaflet.

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

For animal treatment only.
To be supplied only on veterinary prescription.
For external use only.

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Name & Address of the Marketing Authorisation Holder and Manufacturer:

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

Local Representative of the MAH:

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4017

17. MANUFACTURER’S BATCH NUMBER

BN: {number}

Other Information:

POM-VPS

To be supplied only on veterinary prescription.

Bimeda Logo

Barcode

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Pack Label 2.5 L

[There is no carton for the 2.5L pack.

Package leaflet information will be printed on the immediate packaging]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml Pour-on Solution for Sheep
Cypermethrin tech. (cis:trans / 80:20)

2. STATEMENT OF ACTIVE SUBSTANCES

Clear blue non-aqueous solution.
Containing 12.5 mg/ml cypermethrin tech. (cis:trans / 80:20)
Contains Green S Dye (E142)

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

2.5 L

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

Ectofly is for the prevention and treatment of blowfly strike on sheep. Also used for the treatment and control of headflies, and treatment of tick infestation and biting lice on sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-On Solution

Shake well before use.

The product must be applied only with a recommended applicator gun as the product may have a detrimental effect on certain components of standard applicator guns. Full operating and maintenance instructions, including details on the use of nozzles, are supplied with each Pour-On Gun. To ensure accurate dosage of the product, maintain gun carefully.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

On completion of each treatment cycle of the product and before the dosing gun is stored, immediately expel any remaining product in the dosing gun.

Care must be taken not to apply the product right to the lamb's tail as a ewe recognises a young lamb by the smell of the tail area.

This product contains a dye to aid in the identification of treated animals. The colour is temporary and will fade from the fleece within 48 hours of application.

Blowflies

Prevention of blowfly strike

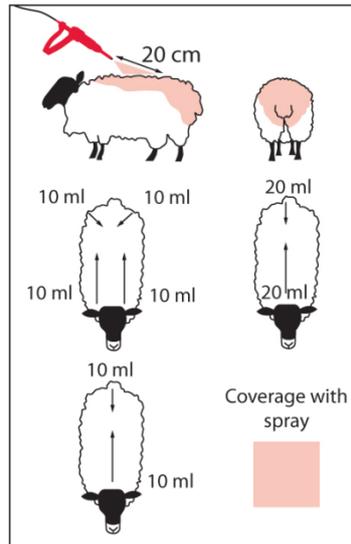
BODYWEIGHT	DOSE	DOSES PER PACK
Up to 25 kg*	20 ml	125
25–40 kg	30 ml	83
Over 40 kg	40 ml	62

* Do not administer to animals of less than 12.5 kg bodyweight.

The dose should be limited to a maximum dose of 40 ml per animal

Apply as a fan-spray to the surface of the fleece on the back and hindquarters of the sheep using the applicator gun fitted with a fan spray nozzle. Half the dose should be applied on the shoulders, back and flanks and half to the rump.

The distance between the nozzle and the fleece should be approximately 20 cm. Each dose will require 2 or 3 sweeps to apply. **THE PRODUCT WILL PREVENT BLOWFLY STRIKE ONLY ON AREAS COVERED BY SPRAY.** One application will give 6–8 weeks protection. Re-treat as required.



Treatment of Blowfly Strike

Apply directly all to the affected parts at the rate of 2.5 ml per 100–150 cm² (roughly the size of a hand). The T-bar nozzle should be used. Most strikes will require 5–10 ml. Ensure that all affected parts are treated. A single application is sufficient to ensure that larvae are expelled and killed within a few hours.

Further Information

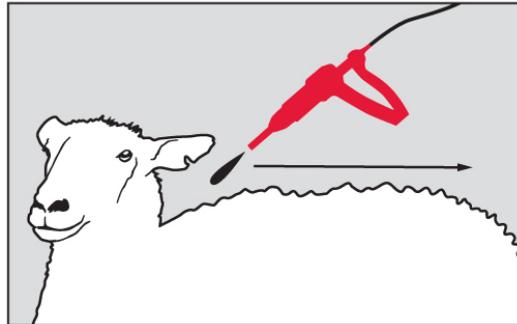
Blowflies are attracted by dirty, damp wool or open wounds. The most common site for flystrike is the rump, due to soiling caused by diarrhoea and urine staining. The efficacy of the product is reduced in the presence of soiled and dirty wool. Therefore sheep must be crutched (dagged) regularly and appropriate worm control measures employed.

Lice

5 ml per 20 kg bodyweight, up to a maximum of 20 ml.

BODYWEIGHT	DOSE	DOSES PER PACK
Up to 20 kg	5 ml	500
21–40 kg	10 ml	250
41-60 kg	15 ml	166
Over 60kg	20 ml	125

Using the straight nozzle on the applicator gun, apply as a pin stream from the shoulders to the rump along the middle of the backline. Sheep may be treated off-shears or anytime during the year.



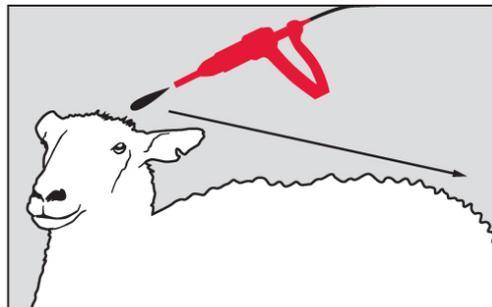
Ticks

Adult sheep and lambs over 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml.

Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

BODYWEIGHT	DOSE	DOSES PER PACK
Up to 10 kg	5 ml	500
11-20 kg	10 ml	250
21-40 kg	20 ml	125
41-60 kg	30 ml	83
Over 60kg	40 ml	62

Using the straight nozzle on the applicator gun, apply as a pin stream from the crown of the head to the top of the rump.

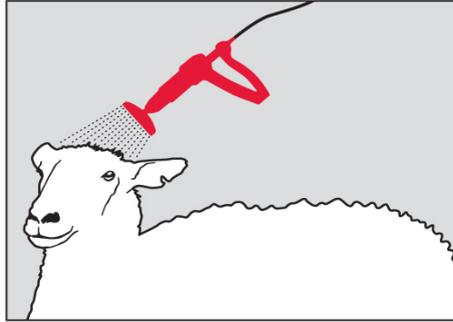


Headflies

5 ml per animal irrespective of size.

Apply to the top of the head between the ears, using the T-bar nozzle. Take care not to apply the product in the sheep's eyes.

One application of the product before the start of the headfly season will give up to 4 weeks protection. Re-treat as required.



8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 8 days.

Milk: 5 days

9. SPECIAL WARNING(S), IF NECESSARY

CONTRAINDICATIONS AND PRECAUTIONS:

Not to be used in lambs less than 1 week old.

For the prevention of blowfly strike, do not administer to animals of less than 12.5 kg bodyweight.

Avoid treating very young lambs if the weather is unseasonably hot.

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

Take care not to apply in the sheep's eyes. This precaution should be observed particularly when treating breeds with little wool on their heads.

May be used during pregnancy. Pregnant Ewes must be handled with care.

If you notice any serious effects not mentioned in this label, please inform your veterinary surgeon.

Toxic signs in mammals are tremors, hyperexcitability, salivation, chorea, athetosis and paralysis, rarely leading to death. Usually, the signs disappear rapidly and the animals recover, generally within a week. There is no specific antidote but symptomatic therapy can be given if considered necessary.

OPERATOR WARNINGS:

- This product is harmful if swallowed and may cause skin, eye or respiratory irritation. This product may also cause hypersensitivity reactions.
- Avoid skin and/or eye contact.
- Avoid children from getting access to the product or treated animals.

- Use in a well-ventilated area and avoid inhaling the vapour.
- Wear eye protection, protective clothing, rubber gloves and boots when applying the product and handling the animal until the product has dried.
- Wear a disposable face-mask when applying as a fan-spray for the prevention of blowfly-strike.
- Make sure when attaching the recommended applicator gun onto the container that the coiled retainer is secured onto the cap and the applicator.
- Wash splashes from skin and eyes immediately with plenty of clean water. If irritation persists seek medical advice immediately and show the package leaflet to the physician.
- Remove contaminated clothing immediately and wash exposed skin with plenty of clean water.
- Do not eat, drink or smoke whilst using the product. Wash hands immediately after use.
- In case of accidental ingestion or mouth contact, immediately rinse the mouth with plenty of water and seek medical advice.

OTHER PRECAUTIONS:

Frequent and repeated use of antiparasiticides from the same class may increase risk of development of resistance.

Cypermethrin is moderately persistent and non-mobile in soil. It is extremely toxic to aquatic invertebrates. Cypermethrin is toxic to dung insects and to honey bees.

Cypermethrin is extremely toxic to aquatic and dung organisms.

As a precautionary measure sheep must be kept away from watercourses for at least 12 hours following treatment. Given the risks to the environment the use of the product should be limited to one treatment per year per pasture.

Long term effects on dung insects caused by continuous or repeated use of pyrethroid ectoparasiticides cannot be excluded. Therefore repeated treatment of animals on the same pasture with a pyrethroid-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

10. EXPIRY DATE

EXP {*month/year*}

Do not use this veterinary medicinal product after the expiry date which is stated on the label {*month/year*}. The expiry date refers to the last day of that month.

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

Once opened use by

Shelf life after first opening the container: 3 months.

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container in a safe place.

Do not store above 25°C.

Protect from direct sunlight.

Store away from food, drink and animal feedstuffs.

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

EXTREMELY DANGEROUS to aquatic invertebrates. Do not contaminate ponds, waterways or ditches with the product or empty container.

Any unused veterinary medicinal product or waste material 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 treatment only.

To be supplied only on veterinary prescription.

For external use only.

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and Manufacturer responsible for batch release:

Bimeda Animal Health Limited

2 / 3 / 4 Airton Close

Tallaght

Dublin 24

Ireland

Local Representative of the MAH:

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4017

1L, 2.5L, 5L and 7.5L pack sizes, not all pack sizes may be marketed

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

Other Information:

POM-VPS

To be supplied only on veterinary prescription.

Date on which the label was last approved: June 2019

Bimeda Logo

Barcode

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Pack Label 5 L

[There is no carton for the 5L pack.

Package leaflet information will be printed on the immediate packaging]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml Pour-on Solution for Sheep
Cypermethrin tech. (cis:trans / 80:20)

2. STATEMENT OF ACTIVE SUBSTANCES

Clear blue non-aqueous solution.
Containing 12.5 mg/ml cypermethrin tech. (cis:trans / 80:20)
Contains Green S Dye (E142)

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

5 L

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

Ectofly is for the prevention and treatment of blowfly strike on sheep. Also used for the treatment and control of headflies, and treatment of tick infestation and biting lice on sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-On Solution

Shake well before use.

The product must be applied only with a recommended applicator gun as the product may have a detrimental effect on certain components of standard applicator guns. Full operating and maintenance instructions, including details on the use of nozzles, are supplied with each Pour-On Gun. To ensure accurate dosage of the product, maintain gun carefully.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

On completion of each treatment cycle of the product and before the dosing gun is stored, immediately expel any remaining product in the dosing gun.

Care must be taken not to apply the product right to the lamb's tail as a ewe recognises a young lamb by the smell of the tail area.

This product contains a dye to aid in the identification of treated animals. The colour is temporary and will fade from the fleece within 48 hours of application.

Blowflies

Prevention of blowfly strike

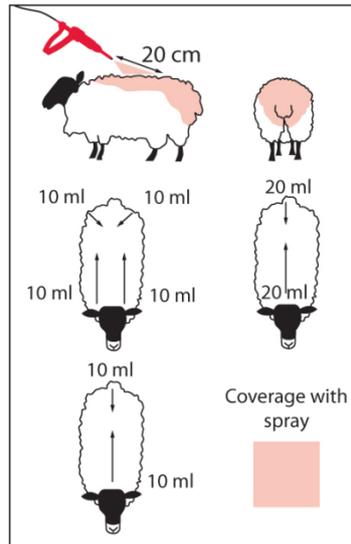
BODYWEIGHT	DOSE	DOSES PER PACK
Up to 25 kg*	20 ml	250
25–40 kg	30 ml	166
Over 40 kg	40 ml	125

* Do not administer to animals of less than 12.5 kg bodyweight.

The dose should be limited to a maximum dose of 40 ml per animal

Apply as a fan-spray to the surface of the fleece on the back and hindquarters of the sheep using the applicator gun fitted with a fan spray nozzle. Half the dose should be applied on the shoulders, back and flanks and half to the rump.

The distance between the nozzle and the fleece should be approximately 20 cm. Each dose will require 2 or 3 sweeps to apply. **THE PRODUCT WILL PREVENT BLOWFLY STRIKE ONLY ON AREAS COVERED BY SPRAY.** One application will give 6–8 weeks protection. Re-treat as required.



Treatment of Blowfly Strike

Apply directly all to the affected parts at the rate of 2.5 ml per 100–150 cm² (roughly the size of a hand). The T-bar nozzle should be used. Most strikes will require 5–10 ml. Ensure that all affected parts are treated. A single application is sufficient to ensure that larvae are expelled and killed within a few hours.

Further Information

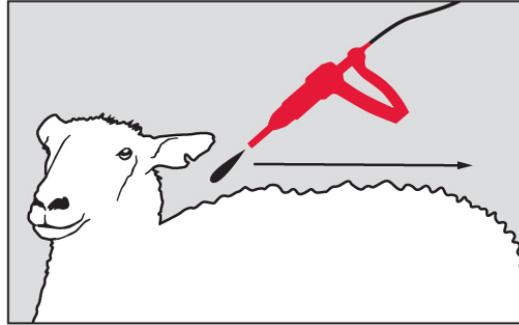
Blowflies are attracted by dirty, damp wool or open wounds. The most common site for flystrike is the rump, due to soiling caused by diarrhoea and urine staining. The efficacy of the product is reduced in the presence of soiled and dirty wool. Therefore sheep must be crutched (dagged) regularly and appropriate worm control measures employed.

Lice

5 ml per 20 kg bodyweight, up to a maximum of 20 ml.

BODYWEIGHT	DOSE	DOSES PER PACK
Up to 20 kg	5 ml	1000
21–40 kg	10 ml	500
41-60 kg	15 ml	333
Over 60kg	20 ml	250

Using the straight nozzle on the applicator gun, apply as a pin stream from the shoulders to the rump along the middle of the backline. Sheep may be treated off-shears or anytime during the year.



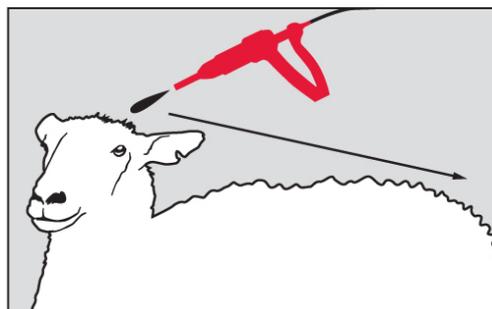
Ticks

Adult sheep and lambs over 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml.

Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

BODYWEIGHT	DOSE	DOSES PER PACK
Up to 10 kg	5 ml	1000
11-20 kg	10 ml	500
21-40 kg	20 ml	250
41-60 kg	30 ml	166
Over 60kg	40 ml	125

Using the straight nozzle on the applicator gun, apply as a pin stream from the crown of the head to the top of the rump.

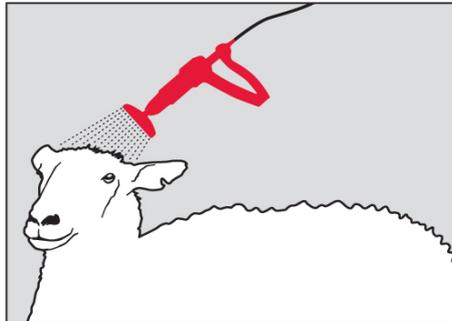


Headflies

5 ml per animal irrespective of size.

Apply to the top of the head between the ears, using the T-bar nozzle. Take care not to apply the product in the sheep's eyes.

One application of the product before the start of the headfly season will give up to 4 weeks protection. Re-treat as required.



8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 8 days.

Milk: 5 days

9. SPECIAL WARNING(S), IF NECESSARY

CONTRAINDICATIONS AND PRECAUTIONS:

Not to be used in lambs less than 1 week old.

For the prevention of blowfly strike, do not administer to animals of less than 12.5 kg bodyweight.

Avoid treating very young lambs if the weather is unseasonably hot.

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

Take care not to apply in the sheep's eyes. This precaution should be observed particularly when treating breeds with little wool on their heads.

May be used during pregnancy. Pregnant Ewes must be handled with care.

If you notice any serious effects not mentioned in this label, please inform your veterinary surgeon.

Toxic signs in mammals are tremors, hyperexcitability, salivation, chorea, athetosis and paralysis, rarely leading to death. Usually, the signs disappear rapidly and the animals recover, generally within a week. There is no specific antidote but symptomatic therapy can be given if considered necessary.

OPERATOR WARNINGS:

- This product is harmful if swallowed and may cause skin, eye or respiratory irritation. This product may also cause hypersensitivity reactions.
- Avoid skin and/or eye contact.
- Avoid children from getting access to the product or treated animals.
- Use in a well-ventilated area and avoid inhaling the vapour.
- Wear eye protection, protective clothing, rubber gloves and boots when applying the product and handling the animal until the product has dried.
- Wear a disposable face-mask when applying as a fan-spray for the prevention of blowfly-strike.
- Make sure when attaching the recommended applicator gun onto the container that the coiled retainer is secured onto the cap and the applicator.
- Wash splashes from skin and eyes immediately with plenty of clean water. If irritation persists seek medical advice immediately and show the package leaflet to the physician.
- Remove contaminated clothing immediately and wash exposed skin with plenty of clean water.
- Do not eat, drink or smoke whilst using the product. Wash hands immediately after use.
- In case of accidental ingestion or mouth contact, immediately rinse the mouth with plenty of water and seek medical advice.

OTHER PRECAUTIONS:

Frequent and repeated use of antiparasitides from the same class may increase risk of development of resistance.

Cypermethrin is moderately persistent and non-mobile in soil. It is extremely toxic to aquatic invertebrates. Cypermethrin is toxic to dung insects and to honey bees.

Cypermethrin is extremely toxic to aquatic and dung organisms.

As a precautionary measure sheep must be kept away from watercourses for at least 12 hours following treatment. Given the risks to the environment the use of the product should be limited to one treatment per year per pasture.

Long term effects on dung insects caused by continuous or repeated use of pyrethroid ectoparasitides cannot be excluded. Therefore repeated treatment of animals on the same pasture with a pyrethroid-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

10. EXPIRY DATE

EXP {*month/year*}

Do not use this veterinary medicinal product after the expiry date which is stated on the label {*month/year*}. The expiry date refers to the last day of that month.

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

Once opened use by

Shelf life after first opening the container: 3 months.

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container in a safe place.

Do not store above 25°C.

Protect from direct sunlight.

Store away from food, drink and animal feedstuffs.

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

EXTREMELY DANGEROUS to aquatic invertebrates. Do not contaminate ponds, waterways or ditches with the product or empty container.

Any unused veterinary medicinal product or waste material 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 treatment only.

To be supplied only on veterinary prescription.

For external use only.

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and Manufacturer responsible for batch release:

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

Local Representative of the MAH:

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4017
1L, 2.5L, 5L and 7.5L pack sizes, not all pack sizes may be marketed

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

Other Information:

POM-VPS

To be supplied only on veterinary prescription.

Date on which the label was last approved: June 2019

Bimeda Logo

Barcode

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGING

7.5 L – carton - *ONLY in IE*

[There is no label for the 7.5L (2.5L&5L) pack.
Package leaflet information will be printed on the immediate packaging of 2.5L and 5L container.]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml Pour-on Solution for Sheep
Cypermethrin tech. (cis:trans / 80:20)

2. STATEMENT OF ACTIVE SUBSTANCES

Clear blue non-aqueous solution.
Containing 12.5 mg/ml cypermethrin tech. (cis:trans / 80:20)
Contains Green S Dye (E142).

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZES

7.5 litre (2.5 litre + 5 litre)

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

For the prevention and treatment of blowfly strike on sheep. Also used for the treatment and control of headflies, and treatment of tick infestation and biting lice on sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-On Solution

SHAKE WELL BEFORE USE.

The product must be applied only with a recommended applicator gun as the product may have a detrimental effect on certain components of standard applicator guns. Full operating and maintenance instructions, including details on the use of nozzles, are supplied with each pour-On Gun. To ensure accurate dosage of the product, maintain gun carefully.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked. On completion of each treatment cycle of the product and before the dosing gun is stored, immediately expel any remaining product in the dosing gun. Care must be taken not to apply the product right to the lamb's tail as a ewe recognises a young lamb by the smell of the tail area.

This product contains a dye to aid in the identification of treated animals. The colour is temporary and will fade from the fleece within 48 hours of application.

Blowflies

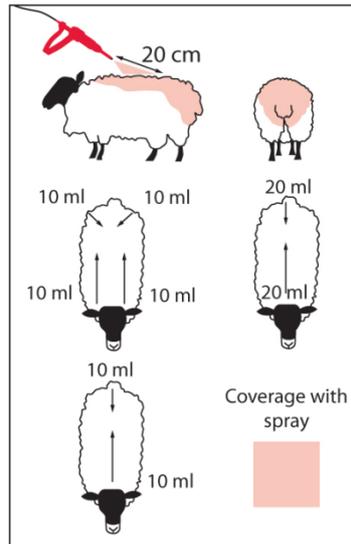
Prevention of blowfly strike

BODYWEIGHT	DOSE	DOSES PER LITRE
Up to 25 kg*	20 ml	50
25–40 kg	30 ml	33
Over 40 kg	40 ml	25

* Do not administer to animals of less than 12.5 kg bodyweight.
The dose should be limited to a maximum dose of 40 ml per animal

Apply as a fan-spray to the surface of the fleece on the back and hindquarters of the sheep using the applicator gun fitted with a fan spray nozzle. Half the dose should be applied on the shoulders, back and flanks and half to the rump.

The distance between the nozzle and the fleece should be approximately 20 cm. Each dose will require 2 or 3 sweeps to apply. **THE PRODUCT WILL PREVENT BLOWFLY STRIKE ONLY ON AREAS COVERED BY SPRAY.** One application will give 6–8 weeks protection. Re-treat as required.



Treatment of Blowfly Strike

Apply directly all to the affected parts at the rate of 2.5 ml per 100–150 cm² (roughly the size of a hand). The T-bar nozzle should be used. Most strikes will require 5–10 ml. Ensure that all affected parts are treated. A single application is sufficient to ensure that larvae are expelled and killed within a few hours.

Further Information

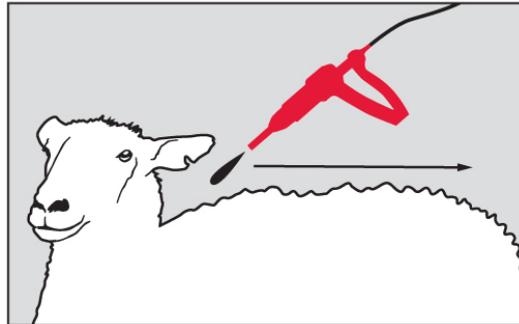
Blowflies are attracted by dirty, damp wool or open wounds. The most common site for flystrike is the rump, due to soiling caused by diarrhoea and urine staining. The efficacy of the product is reduced in the presence of soiled and dirty wool. Therefore sheep must be crutched (dagged) regularly and appropriate worm control measures employed.

Lice

5 ml per 20 kg bodyweight, up to a maximum of 20 ml.

BODYWEIGHT	DOSE	DOSES PER LITRE
Up to 20 kg	5 ml	200
21–40 kg	10 ml	100
41–60 kg	15 ml	66
Over 60kg	20 ml	50

Using the straight nozzle on the applicator gun, apply as a pin stream from the shoulders to the rump along the middle of the backline. Sheep may be treated off-shears or anytime during the year.



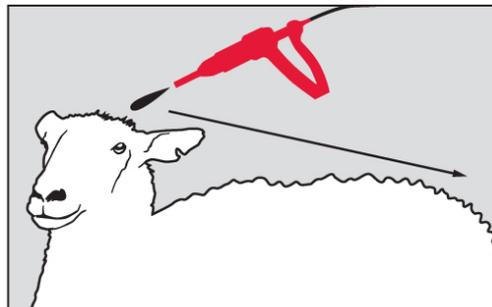
Ticks

Adult sheep and lambs over 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml.

Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

BODYWEIGHT	DOSE	DOSES PER LITRE
Up to 10 kg	5 ml	200
11-20 kg	10 ml	100
21-40 kg	20 ml	50
41-60 kg	30 ml	33
Over 60kg	40 ml	25

Using the straight nozzle on the applicator gun, apply as a pin stream from the crown of the head to the top of the rump.

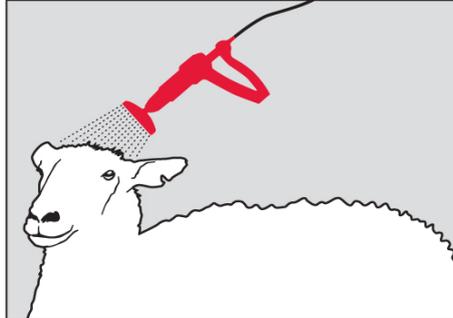


Headflies

5 ml per animal irrespective of size.

Apply to the top of the head between the ears, using the T-bar nozzle. Take care not to apply the product in the sheep's eyes.

One application of the product before the start of the headfly season will give up to 4 weeks protection. Re-treat as required.



8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 8 days.

Milk: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

CONTRAINDICATIONS AND PRECAUTIONS:

Not to be used in lambs less than 1 week old.

For the prevention of blowfly strike, do not administer to animals of less than 12.5 kg bodyweight.

Avoid treating very young lambs if the weather is unseasonably hot.

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

Take care not to apply in the sheep's eyes. This precaution should be observed particularly when treating breeds with little wool on their heads.

May be used during pregnancy. Pregnant Ewes must be handled with care.

If you notice any serious effects not mentioned in this label, please inform your veterinary surgeon.

Toxic signs in mammals are tremors, hyperexcitability, salivation, chorea, athetosis and paralysis, rarely leading to death. Usually, the signs disappear rapidly and the animals recover, generally within a week. There is no specific antidote but symptomatic therapy can be given if considered necessary.

OPERATOR WARNINGS:

- This product is harmful if swallowed and may cause skin, eye or respiratory irritation. This product may also cause hypersensitivity reactions.
- Avoid skin and/or eye contact.
- Avoid children from getting access to the product or treated animals.
- Use in a well-ventilated area and avoid inhaling the vapour.
- Wear eye protection, protective clothing, rubber gloves and boots when applying the product and handling the animal until the product has dried.
- Wear a disposable face-mask when applying as a fan-spray for the prevention of blowfly-strike.
- Make sure when attaching the recommended applicator gun onto the container that the coiled retainer is secured onto the cap and the applicator.
- Wash splashes from skin and eyes immediately with plenty of clean water. If irritation persists seek medical advice immediately and show the package leaflet to the physician.
- Remove contaminated clothing immediately and wash exposed skin with plenty of clean water.
- Do not eat, drink or smoke whilst using the product. Wash hands immediately after use.
- In case of accidental ingestion or mouth contact, immediately rinse the mouth with plenty of water and seek medical advice.

OTHER PRECAUTIONS:

Frequent and repeated use of antiparasitides from the same class may increase risk of development of resistance.

Cypermethrin is moderately persistent and non-mobile in soil. It is extremely toxic to aquatic invertebrates. Cypermethrin is toxic to dung insects and to honey bees.

Cypermethrin is extremely toxic to aquatic and dung organisms.

As a precautionary measure sheep must be kept away from watercourses for at least 12 hours following treatment. Given the risks to the environment the use of the product should be limited to one treatment per year per pasture.

Long term effects on dung insects caused by continuous or repeated use of pyrethroid ectoparasitides cannot be excluded. Therefore repeated treatment of animals on the same pasture with a pyrethroid-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

10. EXPIRY DATE

EXP {*month/year*}

Do not use this veterinary medicinal product after the expiry date which is stated on the label {*month/year*}. The expiry date refers to the last day of that month.

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

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

Once broached use by

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container in a safe place.

Do not store above 25°C.

Protect from direct sunlight.

Store away from food, drink and animal feedstuffs.

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

EXTREMELY DANGEROUS to aquatic invertebrates. Do not contaminate ponds, waterways or ditches with the product or empty container.

Any unused veterinary medicinal product or waste material 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 treatment only.

For external use only.

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

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and Manufacturer responsible for batch release:

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4017

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

Other Information:

POM-VPS

To be supplied only on veterinary prescription.

Bimeda Logo
Barcode

“7.5L ECTOFLY VALUE PACK”

“1x5litre Ectofly
1x2.5litre Ectofly
1x 30ml Applicator”

“Treats 250 x 35kg Lambs”

B. PACKAGE LEAFLET

PACKAGE LEAFLET (for 1L presentation only) Ectofly 12.5 mg/ml Pour-on Solution for Sheep

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

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

Distributed By:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml Pour-On Solution for Sheep
Cypermethrin tech. (cis:trans / 80:20)

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

Clear blue non-aqueous solution

1 ml contains:

Active substance:

Cypermethrin tech. (cis:trans / 80:20) 12.5 mg

Excipient:

Green S Dye (E142). 0.2 mg

4. INDICATION(S)

Ectofly is for prevention and treatment of blowfly strike on sheep. Also used for the treatment and control of headflies, and treatment of tick infestation and biting lice on sheep.

5. CONTRAINDICATIONS

Not to be used in lambs less than one week old.

For the prevention of blowfly strike; do not administer to animals of less than 12.5 kg bodyweight.

Avoid treating very young lambs if the weather is unseasonably hot.

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

6. ADVERSE REACTIONS

None known. If you notice any serious effects or other not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep.

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

Shake well before use.

Administer by means of the recommended applicator gun as follows:

Blowflies:

Prevention of blowfly strike

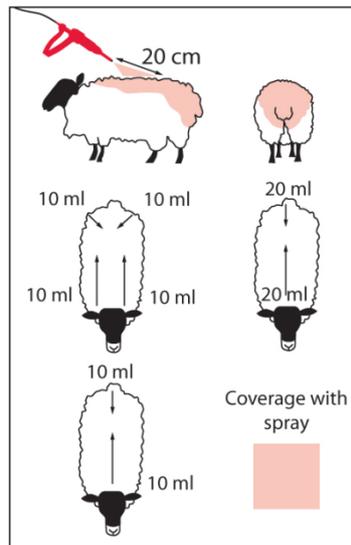
<u>Bodyweight</u>	<u>Dose</u>	<u>Doses per litre</u>
Up to 25 kg*	20 ml	50
25 to 40 kg	30 ml	33
Over 40 kg	40 ml	25

*Do not administer to animals of less than 12.5 kg bodyweight.

The dose should be limited to a maximum dose of 40 ml per animal

Apply as a fan-spray to the surface of the fleece on the back and hindquarters of the sheep using the Pour-On Gun fitted with the fan-spray nozzle. Half the dose should be applied to the shoulders, back and flanks, and half to the rump.

The distance between the nozzle and the fleece should be approximately 20 cm. Each dose will require 2 or 3 sweeps to apply. **THE PRODUCT WILL PREVENT BLOWFLY STRIKE ONLY ON AREAS COVERED BY SPRAY.** One application will give 6-8 weeks protection. Re-treat as required.



Treatment of blowfly strike

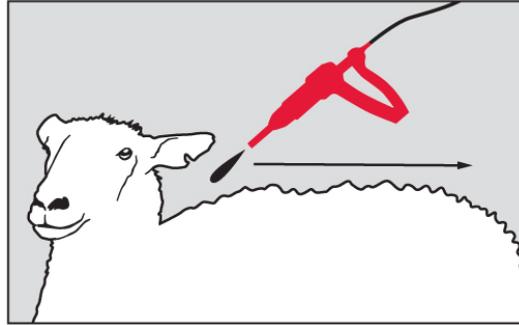
Apply directly to all the affected parts at the rate of 2.5 ml per 100 –150 cm² (roughly the size of a hand). The T-bar nozzle should be used. Most strikes will require 5-10 ml. Ensure that all affected parts are treated. A single application is sufficient to ensure that larvae are expelled and killed within a few hours.

Lice: 5 ml per 20 kg bodyweight up to a maximum of 20 ml.

<u>Bodyweight</u>	<u>Dose</u>	<u>Doses per litre</u>
Up to 20 kg	5 ml	200
21 to 40 kg	10 ml	100
41 to 60 kg	15 ml	66
Over 60 kg	20 ml	50

Using the straight nozzle on the applicator gun, apply as a pin-stream from the shoulders to the rump along the middle of the backline.

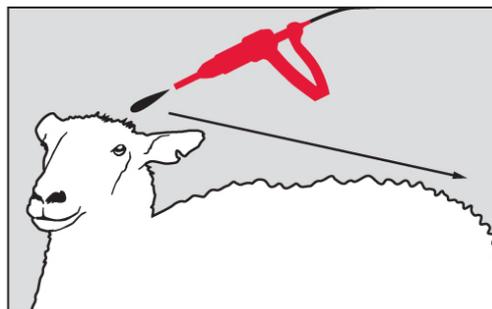
Sheep may be treated off-shears or at any time during the year.



Ticks: Adult sheep and lambs greater than 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml. Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

<u>Bodyweight</u>	<u>Dose</u>	<u>Doses per litre</u>
Up to 10 kg	5 ml	200
11 to 20 kg	10 ml	100
21 to 40 kg	20 ml	50
41 to 60 kg	30 ml	33
Over 60 kg	40 ml	25

Using the straight nozzle on the Pour-On Gun, apply as a pin-stream from the crown of the head to the top of the rump.

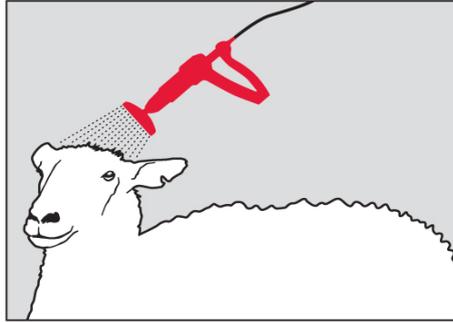


Headflies: 5 ml per animal irrespective of size.

Apply to the top of the head between the ears using the T-bar nozzle.

Take care not to apply product in the sheep's eyes.

One application before the start of the headfly season will give up to 4 weeks protection. Re-treat as required.



This product contains a dye to aid in the identification of treated animals. The colour is temporary and will fade from the fleece within 48 hours of application.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

On completion of each treatment cycle of the product and before the dosing gun is stored, immediately expel any remaining product in the dosing gun.

Shake well before use.

10. WITHDRAWAL PERIODS

Meat and offal: 8 days.

Milk: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.

Do not store above 25°C.

Protect from direct sunlight.

Store in tightly closed original container in a safe place.

Store 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

{month/year}. The expiry date refers to the last day of that month.

When the container is broached (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 carton should be discarded should be worked out. This discard date should be written in the space provided.

Shelf life after first opening the container: 3 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Frequent and repeated use of antiparasitics from the same class may increase risk of development of resistance.

Special precautions for use in animals:

Care must be taken not to apply the product right to the lamb's tail, as a ewe recognises a young lamb partly by the smell of the tail area.

Blowflies are attracted by dirty, damp wool or open wounds. The most common site for fly strike is the rump due to soiling caused by diarrhoea and urine staining. The efficacy of the product is reduced in the presence of soiled or dirty wool. Therefore, sheep must be crutched (dagged) regularly and appropriate worm control measures employed.

Take care not to apply product in the sheep's eyes. This precaution should be observed particularly when treating breeds with little wool on their heads.

The product must be applied only with the recommended applicator gun, as the product may have a detrimental effect on certain components of conventional dosing guns.

Full operating and maintenance instructions, including details on the use of nozzles are supplied with each Pour-On Gun. Please read carefully before use. Maintain gun carefully to ensure accurate dosage.

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

- This product is harmful if swallowed and may cause skin, eye or respiratory irritation. This product may also cause hypersensitivity reactions.
- Avoid skin and/or eye contact.
- Avoid children from getting access to the product or treated animals.
- Use in a well-ventilated area and avoid inhaling the vapour.
- Wear eye protection, protective clothing, rubber gloves and boots when applying the product and handling the animal until the product has dried.
- Wear a disposable face-mask when applying as a fan-spray for the prevention of blowfly-strike.
- Make sure when attaching the recommended applicator gun onto the container that the coiled retainer is secured onto the cap and the applicator.
- Wash splashes from skin and eyes immediately with plenty of clean water. If irritation persists seek medical advice immediately and show the package leaflet to the physician.

- Remove contaminated clothing immediately and wash exposed skin with plenty of clean water.
- Do not eat, drink or smoke whilst using the product. Wash hands immediately after use.
- In case of accidental ingestion or mouth contact, immediately rinse the mouth with plenty of water and seek medical advice.

Other precautions:

Cypermethrin is moderately persistent and non-mobile in soil. It is extremely toxic to aquatic invertebrates. Cypermethrin is toxic to dung insects and to honey bees.

Cypermethrin is extremely toxic to aquatic and dung organisms. As a precautionary measure sheep must be kept away from watercourses for at least 12 hours following treatment.

Given the risks to the environment the use of the product should be limited to one treatment per year per pasture.

Long term effects on dung insects caused by continuous or repeated use of pyrethroid ectoparasiticides cannot be excluded. Therefore repeated treatment of animals on the same pasture with a pyrethroid-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

Pregnancy:

Can be used during pregnancy. Pregnant Ewes must be handled with care. If you notice any serious effects not mentioned in this label, please inform your veterinary surgeon.

Overdose (symptoms, emergency procedures, antidotes):

Toxic signs in mammals are tremors, hyperexcitability, salivation, chorea, athetosis and paralysis, rarely leading to death. Usually the signs disappear rapidly and the animals recover, generally within a week. There is no specific antidote but symptomatic therapy can be given if necessary.

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

EXTREMELY DANGEROUS to aquatic invertebrates. Do not contaminate ponds, waterways or ditches with the product or empty container.

Any unused veterinary medicinal product or waste material 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

August 2019

15. OTHER INFORMATION

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

For external use only.

1L, 2.5L 5L and 7.5litre (2.5 litre + 5 litre) pack sizes available
Not all pack sizes may be marketed.

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

Approved 20 September 2019

