ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml pour-on solution for sheep (IE, FR, RO, UK (NI))

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:

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

Excipient:

<Qualitative composition of excipients and other constituents>	**<Quantitative composition if that information is essential for proper administration of the veterinary medicinal product>**
Green S Dye (E142)	0.2 mg
Diethylene glycol monobutyl ether	

Clear blue non-aqueous solution

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the treatment and control of headflies, and treatment of tick infestation and biting lice. For the prevention and treatment of blowfly strike.

3.3 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 cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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

3.5 Special precautions for use

<u>Special precautions for safe use in the target species:</u>

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.

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.

For external use only.

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.

Special precautions for the protection of the environment:

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 (see 'Environmental properties'). 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.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy. Pregnant ewes must be handled with care.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

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.

Administer by means of the recommended applicator gun as follows:

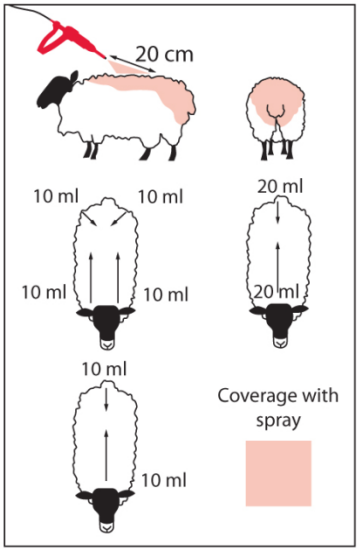
Blowflies:

Prevention of blowfly strike

Bodyweight	Dose	Doses per litre
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.



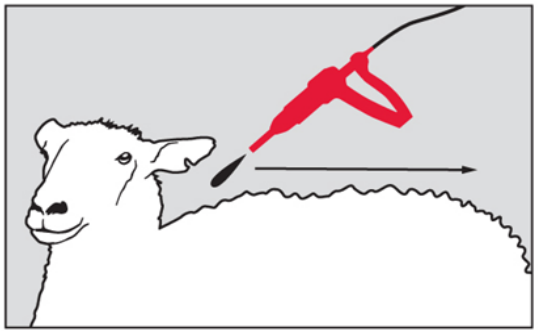
Treatment of blowfly strike

Apply directly to all the affected parts at the rate of 2.5 ml per 100 –150 cm^2 (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.

Bodyweight	Dose	Doses per litre
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

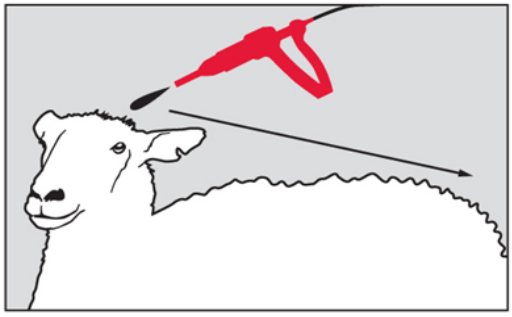
Using the straight nozzle on the applicator gun, apply as a pin-stream from the shoulders to the rump along the middle of the backline.
Sheep may be treated off-shears or at any time during the year.



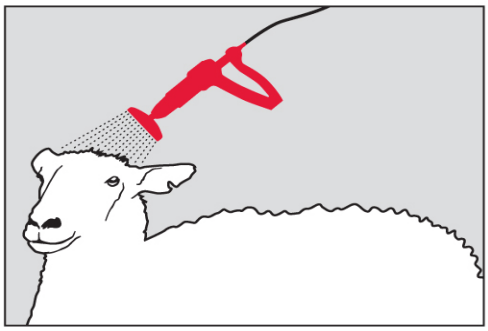
Ticks: Adult sheep and lambs greater than 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml. Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

Bodyweight	Dose	Doses per litre
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 considered necessary.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 8 days.

Milk: 5 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QP53AC08

4.2 Pharmacodynamics

Cypermethrin is a neuropoison acting on the axons in the peripheral and central nervous system of insects by interacting with sodium channels.

4.3 Pharmacokinetics

Synthetic pyrethroids are generally metabolised in mammals through ester hydrolysis, oxidation and conjugation and there is no tendency to accumulate in tissues.

Environmental properties
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. Long term effects on dung insects caused by continuous or repeated use of the product cannot be excluded.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 Years.
Shelf life after first opening of the immediate packaging: 3 months.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

White high-density polyethylene flat bottom containers with polypropylene closures and induction heat-sealed wadding,

1 L bottle
2.5 L bottle
5 L bottle
Box of 1 x 5 L bottle and 1 x 2.5 L bottle

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as Cypermethrin is EXTREMLY DANGEROUS for fish and other aquatic organisms.
Do not contaminate ponds, waterways or ditches with the product or empty container.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{1L/Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml pour-on solution (IE, FR, RO, UK (NI))

2. STATEMENT OF ACTIVE SUBSTANCES

Containing 12.5 mg/ml cypermethrin (cis:trans / 80:20)

3. PACKAGE SIZE

1 L

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-On Solution
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 8 days.
Milk: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by
Once opened use within 3 months

9. SPECIAL STORAGE PRECAUTIONS

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.

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

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1L Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml pour-on solution (IE, FR, RO, UK (NI))

2. STATEMENT OF ACTIVE SUBSTANCES

Containing 12.5 mg/ml cypermethrin (cis:trans / 80:20)

3. TARGET SPECIES

Sheep

4. ROUTES OF ADMINISTRATION

Pour-On Solution

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 8 days.
Milk: 5 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by
Once opened use within 3 months

7. SPECIAL STORAGE PRECAUTIONS

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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Ltd.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ectofly 12.5 mg/ml pour-on solution for sheep(IE, FR, RO, UK (NI))

2. Composition

Each ml contains

Active substance:

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

Excipients:
Green S Dye (E142). …….0.2 mg

Clear blue non-aqueous solution

3. Target species

Sheep

4. Indications for use

Ectofly is for prevention and treatment of blowfly strike on sheep. Also used for the treatment and control of head flies, 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 cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

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

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
Cypermethrin is moderately persistent and non-mobile in soil. It is extremely toxic to aquatic invertebrates. Cypermethrin is toxic to dung insects and to honeybees.
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.

Interaction with other medicinal products and other forms of interaction:
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.

Overdose:
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.

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 in this package leaflet, 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 at the end of this leaflet, or via your national reporting system:

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

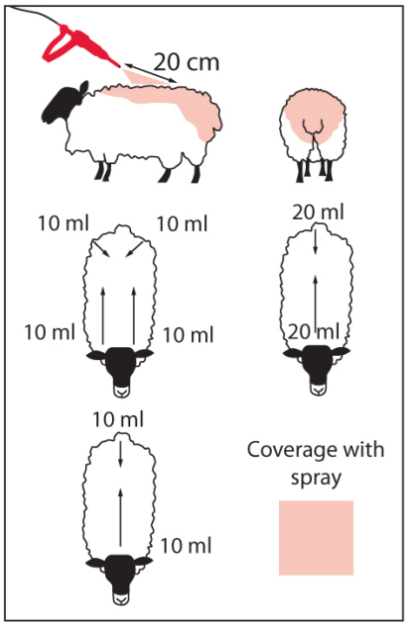
Administer by means of the recommended applicator gun as follows:

Blowflies:
Prevention of blowfly strike

Bodyweight	Dose	Doses per litre
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.

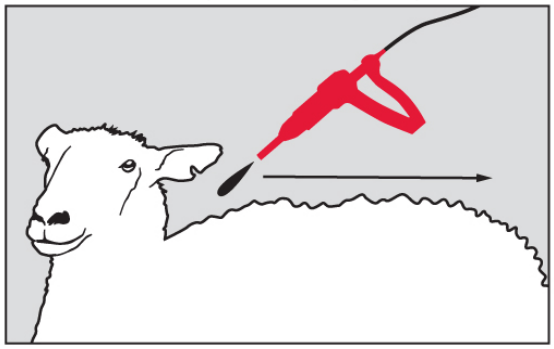


Treatment of blowfly strike
Apply directly to all the affected parts at the rate of 2.5 ml per 100 –150 cm2 (roughly the size of a hand). The T-bar nozzle should be used. Most strikes will require 5-10 ml. Ensure that all affected parts are treated. A single application is sufficient to ensure that larvae are expelled and killed within a few hours.
Lice: 5 ml per 20 kg bodyweight up to a maximum of 20 ml.

Bodyweight	Dose	Doses per litre
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

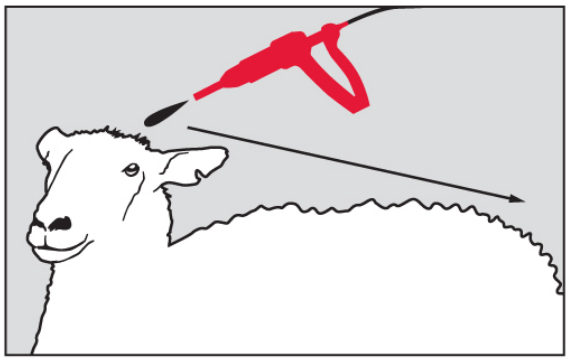
Using the straight nozzle on the applicator gun, apply as a pin-stream from the shoulders to the rump along the middle of the backline.
Sheep may be treated off-shears or at any time during the year.



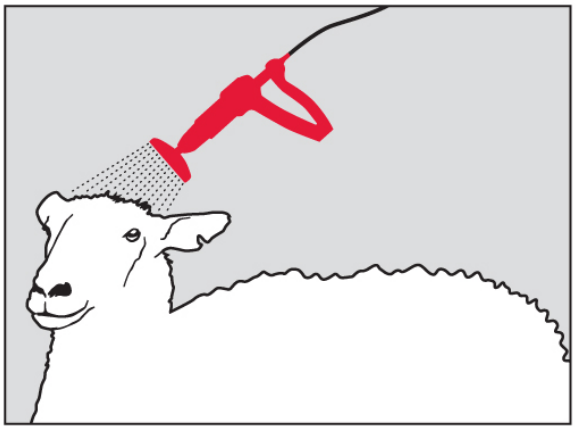
Ticks: Adult sheep and lambs greater than 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml. Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

Bodyweight	Dose	Doses per litre
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 the 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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as Cypermethrin is EXTREMELY DANGEROUS for fish and other aquatic organisms.
Do not contaminate ponds, waterways or ditches with the product or empty container.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription

14. Marketing authorisation numbers and pack sizes

1 L bottle
2.5 L bottle
5 L bottle
Box of 1 x 5 L bottle and 1 x 2.5 L bottleNot 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).

16. Contact details

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

Bimeda Animal Health Ltd,
2, 3 & 4 Airton Close,
Tallaght,
Dublin 24
Ireland
Tel: 01 4667900

17. Other information

For animal treatment only.
For external use only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

2.5L & 5L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ectofly 12.5 mg/ml pour-on solution for sheep(IE, FR, IT, RO, UK (NI))

2. COMPOSITION

Each ml contains
Active substance:
Cypermethrin tech. (cis:trans / 80:20)…… 12.5 mg

Excipient:
Green S Dye (E142)…….. 0.2 mg

Clear blue non-aqueous solution

3. PACKAGE SIZE

2.5L
5L

4. TARGET SPECIES

Sheep

5. INDICATIONS FOR USE

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

6. CONTRAINDICATIONS

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 cases of hypersensitivity to the active substance or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

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

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
Cypermethrin is moderately persistent and non-mobile in soil. It is extremely toxic to aquatic invertebrates. Cypermethrin is toxic to dung insects and to honeybees.
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.

Interactions with other medicinal products and other forms of interaction:
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.

Overdose:
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.

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 in this package leaflet, 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 at the end of this leaflet, or via your national reporting system:

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

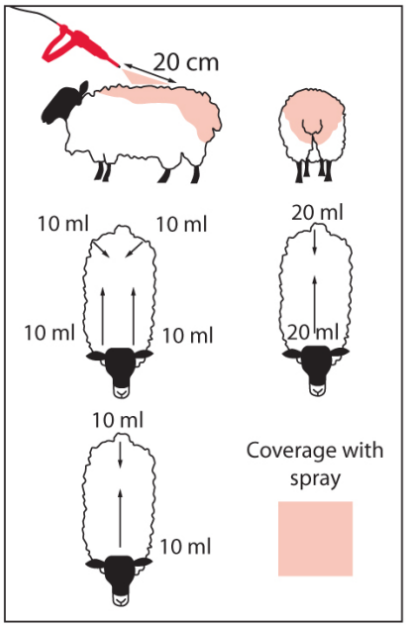
Dosage for each species, routes and method of administration
Administer by means of the recommended applicator gun as follows:

Blowflies:
Prevention of blowfly strike

Bodyweight	Dose	Doses per litre
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.

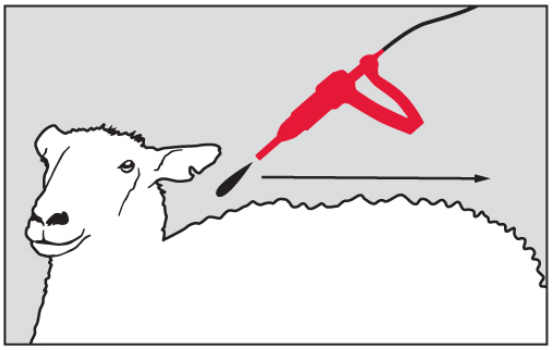


Treatment of blowfly strike
Apply directly to all the affected parts at the rate of 2.5 ml per 100 –150 cm2 (roughly the size of a hand). The T-bar nozzle should be used. Most strikes will require 5-10 ml. Ensure that all affected parts are treated. A single application is sufficient to ensure that larvae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

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

Bodyweight	Dose	Doses per litre
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

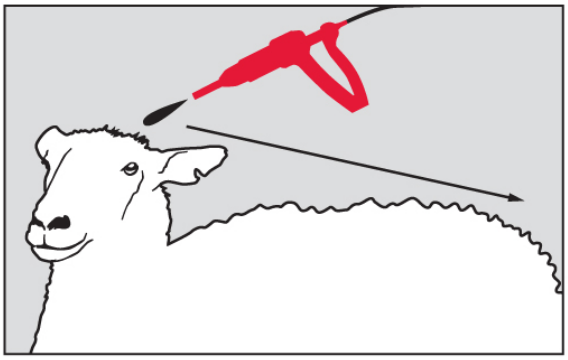
Using the straight nozzle on the applicator gun, apply as a pin-stream from the shoulders to the rump along the middle of the backline.
Sheep may be treated off-shears or at any time during the year.



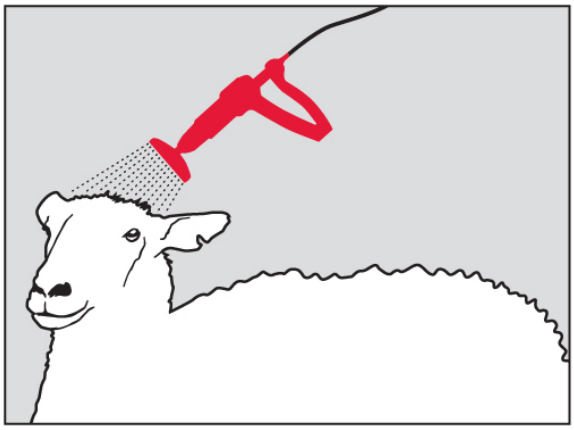
Ticks: Adult sheep and lambs greater than 10 kg: 10 ml per 20 kg bodyweight, up to a maximum of 40 ml. Lambs under 10 kg: 5 ml followed 3 weeks later by a 10 ml application.

Bodyweight	Dose	Doses per litre
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.

10. ADVICE ON CORRECT ADMINISTRATION

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.

11. WITHDRAWAL PERIODS

Withdrawal periods
Meat and offal: 8 days.
Milk: 5 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the 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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as Cypermethrin is EXTREMELY DANGEROUS for fish and other aquatic organisms.
Do not contaminate ponds, waterways or ditches with the product or empty container.

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
1 L bottle
2.5 L bottle
5 L bottle
Box of 1 x 5 L bottle and 1 x 2.5 L bottleNot 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 Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Bimeda Animal Health Ltd,
2, 3 & 4 Airton Close,
Tallaght,
Dublin 24
Ireland
Tel: 01 4667900

18. OTHER INFORMATION

Other information
For external use only.

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}
Once broached use by

Shelf life after first opening the immediate packaging: 3 months.

21. BATCH NUMBER

Lot {number}