ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Protect 7.5 mg/ml pour-on suspension for cattle and sheep

DK: Butoxvet 7.5 mg/ml pour-on suspension for cattle and sheep
SE: Blaze vet 7.5 mg/ml pour-on suspension for cattle and sheep
FI: Butox vet 7.5 mg/ml pour-on suspension for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Deltamethrin 7.50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formaldehyde solution 35 %	0.18 mg
Sodium laurilsulfate	
Silica, precipitated	
Xanthan gum	
Citric acid monohydrate	
Propylene glycol	
Water, purified	
Rhodorsil antifoam 416	
Rhodorsil antifoam 426R	
Dispersing agent SI	

Off-white to pale brown pour-on suspension

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep

3.2 Indications for use for each target species

Cattle:
For the treatment and prevention of infestations with the following ectoparasites:
Sucking lice (*Linognathus vituli, Haematopinus eurysternus*)
Biting lice (*Bovicola bovis*)

For the control of:
Stinging flies (*Stomoxys calcitrans, Haematobia* spp.) as well as nuisance flies (*Musca* spp., *Hippobosca* spp.)

Sheep:

For the treatment and prevention of infestations with the following ectoparasites:
Sucking lice (*Linognathus ovillus*)
Biting lice (*Bovicola ovis*)
Sheep keds (*Melophagus ovinus*)

3.3 Contraindications

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

3.4 Special warnings

Animals should not be treated during heat-waves (danger of animals licking off the product).
Do not apply on or near the animal's eyes and mucous membranes.
Care should be taken to avoid practices like too frequent and repeated use of insecticides from the same class over an extended period of time, because they increase the risk of development of resistance and could ultimately result in ineffective therapy.
This veterinary medicinal product is a fly control product which will reduce the number of flies resting directly on the animal but it is not expected to eliminate all flies on a farm.
Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle and lice in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of stinging and nuisance flies and lice.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Resistance cannot be ruled out in nuisance flies (*Musca* spp.). . This veterinary medicinal product should be used in the context of a management concept to combat flies by improving the status of hygiene and the use of non-chemical substances primarily. In addition, the alternating use of insecticides of different active substance groups should be considered on the basis of a pest elimination program. The choice of the active substance should be based ideally on a susceptibility testing. Please ask your veterinary surgeon for further information.
This veterinary medicinal product should only be administered onto undamaged skin as toxicity is possible due to absorption from major skin lesions. However, signs of local irritation may occur after treatment as skin may be already affected by infestation. Deltamethrin is locally irritant to eyes and mucous membranes.

The presence of a mixed infestation should be established before treatment.
The presence of a mixed infestation with ectoparasites not indicated on the labelling should be established before treatment.

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

Irritation, sensitization, and adverse effects on the neuronal system might occur.
Avoid contact with skin, eyes and mucous membranes, and oral uptake.
Wear protective gloves.
Change heavily contaminated clothes and wash before re-use.
Do not eat, drink or smoke while using this veterinary medicinal product.
In case of skin contact, wash the exposed parts thoroughly with water and soap.
In case of contact with eyes, immediately rinse thoroughly with water.
People with known hypersensitivity to this veterinary medicinal product should avoid contact with the veterinary medicinal product.
If you feel unwell after the use of this veterinary medicinal product seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
The long-term effects of the VMP on the population dynamics of dung beetles have not been investigated; therefore, it is advisable not to treat animals on the same pasture every season.

3.6 Adverse events

Cattle, sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Skin irritation (such as erythema, pruritus) Restlessness, hyperactivity, anxiety, behavioural disorder* Hypersensitivity

* Tossing heads and tails

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 the local representative of the marketing authorisation holder> or the national competent authority via the national reporting system. See also section `contact details` of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

In combination with organo-phosphorous substances, the toxicity of deltamethrin is enhanced. Therefore, it is not advisable to use such products in combination with this veterinary medicinal product.

3.9 Administration routes and dosage

Pour-on use.

Shake well before use.

For the 250 ml and 1000 ml bottles: screw on the applicator as described on the package insert.
For the 2500 ml bottle: connect applicator gun with attached tube and connection screw-cap.
Pour on the product evenly along the backline of the animals from the base of the head to the tail.

Flies:
Cattle

Up to 100 kg bodyweight:	10 ml
100 to 300 kg bodyweight:	20 ml
More than 300 kg bodyweight:	30 ml

Sucking and biting lice as well as sheep keds:
Cattle, Sheep
10 ml per animal

The following points have to be considered for the treatment of sheep:
- treat shortly after shearing (animals with short fleece)
- keep shorn group away from non-shorn animals
- shear and treat ewes 4-6 weeks before parturition

The veterinary medicinal product is administered as a single treatment.
However, treatment against flies can be repeated every 6-10 weeks, depending on the infestation degree. The duration of control for Musca spp. may vary.

The influence of weather on the duration of efficacy has not been investigated.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Deltamethrin is of very low toxicity when administered topically as an aqueous suspension. Therefore, acute toxicity through transdermal absorption is not expected.
Overdoses of three times the recommended dose did not induce any adverse effects in cattle. An accidental oral intake of a large quantity or the existence of extensive skin lesions can lead to signs of toxicity such as salivation, excitement, clonic convulsions and paresthesias. A veterinarian should be consulted. The therapy has to be symptomatic and supportive.

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

Cattle:
Meat and offal: 18 days
Milk: 0 days

Sheep:
Meat and offal: 1 day
Milk: 12 hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QP53AC11

4.2 Pharmacodynamics

Deltamethrin is a synthetic pyrethroid which is, like other substances of this class, structurally based on naturally occurring plant pyrethrins.

Pyrethroids are insecticidal and acaricidal by contact. The target is the voltage-dependent sodium channel in the nerve membrane. The effect is prolonged opening of the sodium channels. The characteristic symptoms in arthropods are an initial period of excitement followed by coordination problems and, after a sufficient period of exposure, paralysis and death (killing effect).

4.3 Pharmacokinetics

Due to its lipophilic nature, deltamethrin can accumulate in fat. The dermal absorption after use of a pour-on formulation is relatively minor. It is metabolised by ester hydrolysis, oxidation and conjugation. Non-metabolised deltamethrin is mainly excreted via the feces. The metabolites are mainly excreted via the urine. Only a minor part of deltamethrin is traceable in milk.

Environmental properties
Deltamethrin is toxic to bees and dung breeding insects. Deltamethrin is also toxic to fish and other aquatic organisms.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 30 weeks

5.3 Special precautions for storage

Do not refrigerate or freeze. Protect from frost.

5.4 Nature and composition of immediate packaging

250 ml and 1000 ml HDPE bottle in a carton box include an integrated dosing chamber and a screw-on applicator.
2500 ml HDPE bottle packed with an applicator gun to be tube-connected to the 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 deltamethrin may be dangerous for fish and other aquatic organisms.

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

{to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

<{DD/MM/YYYY}>

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

<{DD/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

250 ml, 1000 ml Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Protect 7.5 mg/ml pour-on suspension

DK: Butoxvet 7.5 mg/ml pour-on suspension
SE: Blaze vet 7.5 mg/ml pour-on suspension
FI: Butox vet 7.5 mg/ml pour-on suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Deltamethrin 7.50 mg/ml

3. PACKAGE SIZE

250 ml
1000 ml

4. TARGET SPECIES

Cattle, sheep

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
Meat and offal: 18 days
Milk: 0 days

Sheep:
Meat and offal: 1 day
Milk: 12 hours

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 30 weeks
Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze. Protect from frost.

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

{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{to be completed nationally}

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

250 ml, 1000 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Protect 7.5 mg/ml pour-on suspension

DK: Butoxvet 7.5 mg/ml pour-on suspension
SE: Blaze vet 7.5 mg/ml pour-on suspension
FI: Butox vet 7.5 mg/ml pour-on suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Deltamethrin 7.50 mg/ml

3. TARGET SPECIES

Cattle, sheep

4. ROUTES OF ADMINISTRATION

Pour-on use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
Meat and offal: 18 days
Milk: 0 days

Sheep:
Meat and offal: 1 day
Milk: 12 hours

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 30 weeks
Once opened use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze. Protect from frost.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

{to be completed nationally}

9. BATCH NUMBER

Lot {number}

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

2500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Protect 7.5 mg/ml pour-on suspension for cattle and sheep

DK: Butoxvet 7.5 mg/ml pour-on suspension for cattle and sheep
SE: Blaze vet 7.5 mg/ml pour-on suspension for cattle and sheep
FI: Butox vet 7.5 mg/ml pour-on suspension for cattle and sheep

2. COMPOSITION

Each ml contains:

Active substance:
Deltamethrin 7.50 mg

Excipients:
Formaldehyde solution 35 % 0.18 mg

Off-white to pale brown pour-on suspension

3. PACKAGE SIZE

250 ml
1000 ml
2500 ml

4. TARGET SPECIES

Cattle, sheep

5. INDICATIONS FOR USE

Indications for use
Cattle:
For the treatment and prevention of infestations with the following ectoparasites:
– sucking lice (*Linognathus vituli, Haematopinus eurysternus*)
– biting lice (*Bovicola bovis*)
For the control of:
– stinging flies (*Stomoxys calcitrans, Haematobia* spp.) as well as nuisance flies (*Musca* spp.*, Hippobosca* spp.)

Sheep:
or the treatment and prevention of infestations with the following ectoparasites:
– sucking lice (*Linognathus ovillus*)
– biting lice (*Bovicola ovis*)
- sheep keds (*Melophagus ovinus*)

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

Special warnings:
Animals should not be treated during heat-waves (danger of animals licking off the product).
Do not apply on or near the animal's eyes and mucous membranes.
Care should be taken to avoid practices like too frequent and repeated use of insecticides from the same class over an extended period of time, because they increase the risk of development of resistance and could ultimately result in ineffective therapy.
This veterinary medicinal product is a fly control product which will reduce the number of flies resting directly on the animal but it is not expected to eliminate all flies on a farm.
Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle and lice in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of stinging and nuisance flies and lice.

Special precautions for safe use in the target species:
Resistance cannot be ruled out in nuisance flies (*Musca* spp.). This veterinary medicinal product should be used in the context of a management concept to combat flies by improving the status of hygiene and the use of non-chemical substances primarily. In addition, the alternating use of insecticides of different active substance groups should be considered on the basis of a pest elimination program. The choice of the active substance should be based ideally on a susceptibility testing. Please ask your veterinary surgeon for further information.
This veterinary medicinal product should only be administered onto undamaged skin as toxicity is possible due to absorption from major skin lesions. However, signs of local irritation may occur after treatment as skin may be already affected by infestation. Deltamethrin is locally irritant to eyes and mucous membranes.

The presence of a mixed infestation should be established before treatment.
The presence of a mixed infestation with ectoparasites not indicated on the labelling should be established before treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Irritation, sensitization, and adverse effects on the neuronal system might occur.
Avoid contact with skin, eyes and mucous membranes, and oral uptake.
Wear protective gloves.
Change heavily contaminated clothes and wash before re-use.
Do not eat, drink or smoke while using this veterinary medicinal product.
In case of skin contact, wash the exposed parts thoroughly with water and soap.
In case of contact with eyes, immediately rinse thoroughly with water.
People with known hypersensitivity to this veterinary medicinal product should avoid contact with the veterinary medicinal product.
If you feel unwell after the use of this veterinary medicinal product seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

The long-term effects of the VMP on the population dynamics of dung beetles have not been investigated; therefore, it is advisable not to treat animals on the same pasture every season.

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:
In combination with organo-phosphorous substances, the toxicity of deltamethrin is enhanced. Therefore, it is not advisable to use such products in combination with this veterinary medicinal product.

Overdose:
Deltamethrin is of very low toxicity when administered topically as an aqueous suspension. Therefore, acute toxicity through transdermal absorption is not expected.
Overdoses of three times the recommended dose did not induce any adverse effects in cattle. An accidental oral intake of a large quantity or the existence of extensive skin lesions can lead to signs of toxicity such as salivation, excitement, clonic convulsions and paresthesias. A veterinarian should be consulted. The therapy has to be symptomatic and supportive.

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

8. ADVERSE EVENTS

Adverse events

Cattle, sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Skin irritation (such as erythema, pruritus) Restlessness, hyperactivity, anxiety, behavioural disorder* Hypersensitivity

* Tossing heads and tails

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

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

Dosage for each species, routes and method of administration
Pour-on use. Shake well before use.
Connect applicator gun with attached tube and connection screw-cap.
Pour on the product evenly along the backline of the animals from the base of the head to the tail.

Flies:

Cattle
Up to 100 kg bodyweight: 10 ml
100 to 300 kg bodyweight: 20 ml
More than 300 kg bodyweight: 30 ml

Sucking and biting lice as well as sheep keds:
Cattle, Sheep
10 ml per animal

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

The following points have to be considered for the treatment of sheep:
- treat shortly after shearing (animals with short fleece)
- keep shorn group away from non-shorn animals
- shear and treat ewes 4-6 weeks before parturition

The veterinary medicinal product is administered as a single treatment.
However, treatment against flies can be repeated every 6-10 weeks, depending on the infestation degree. The duration of control for *Musca* spp. may vary.
The influence of weather on the duration of efficacy has not been investigated.

11. WITHDRAWAL PERIODS

Withdrawal periods
Cattle:
Meat and offal: 18 days
Milk: 0 days

Sheep:
Meat and offal: 1 day
Milk: 12 hours

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Do not refrigerate or freeze. Protect from frost.

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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

This veterinary medicinal product should not enter water courses as deltamethrin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

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

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

{to be adapted nationally}

Pack sizes
250 ml and 1000 ml HDPE bottle in a carton box include an integrated dosing chamber and a screw-on applicator.
2500 ml HDPE bottle packed with an applicator gun to be tube-connected to the bottle.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{DD/MM/YYYY}

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

17. CONTACT DETAILS

Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
{to be adapted nationally}

Manufacturer responsible for batch release:
Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

<Local representatives <and contact details to report suspected adverse reactions>:>
{to be adapted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{to be adapted nationally}

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use by …
Shelf life after first opening the immediate packaging: 30 weeks

21. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Butox Protect 7.5 mg/ml pour-on suspension for cattle and sheep

DK: Butoxvet 7.5 mg/ml pour-on suspension for cattle and sheep
SE: Blaze vet 7.5 mg/ml pour-on suspension for cattle and sheep
FI: Butox vet 7.5 mg/ml pour-on suspension for cattle and sheep

2. Composition

Each ml contains:

Active substance:
Deltamethrin 7.50 mg

Excipients:
Formaldehyde solution 35 % 0.18 mg

Off-white to pale brown pour-on suspension

3. Target species

Cattle, sheep

4. Indications for use

Cattle:
For the treatment and prevention of infestations with the following ectoparasites:
- sucking lice (*Linognathus vituli, Haematopinus eurysternus*)
- biting lice (*Bovicola bovis*)

For the control of:
- stinging flies (*Stomoxys calcitrans, Haematobia* spp.) as well as nuisance flies (*Musca* spp*., Hippobosca* spp.)

Sheep:
For the treatment and prevention of infestations with the following ectoparasites:
- sucking lice (*Linognathus ovillus*)
- biting lice (*Bovicola ovis*)
- sheep keds (*Melophagus ovinus*)

5. Contraindications

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

6. Special warnings

Special warnings:
Animals should not be treated during heat-waves (danger of animals licking off the product).
Do not apply on or near the animal's eyes and mucous membranes.
Care should be taken to avoid practices like too frequent and repeated use of insecticides from the same class over an extended period of time, because they increase the risk of development of resistance and could ultimately result in ineffective therapy.

This veterinary medicinal product is a fly control product which will reduce the number of flies resting directly on the animal but it is not expected to eliminate all flies on a farm.
Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle and lice in sheep. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of stinging and nuisance flies and lice.

Special precautions for safe use in the target species:
Resistance cannot be ruled out in nuisance flies (*Musca* spp.). This veterinary medicinal product should be used in the context of a management concept to combat flies by improving the status of hygiene and the use of non-chemical substances primarily. In addition, the alternating use of insecticides of different active substance groups should be considered on the basis of a pest elimination program. The choice of the active substance should be based ideally on a susceptibility testing. Please ask your veterinary surgeon for further information.
This veterinary medicinal product should only be administered onto undamaged skin as toxicity is possible due to absorption from major skin lesions. However, signs of local irritation may occur after treatment as skin may be already affected by infestation. Deltamethrin is locally irritant to eyes and mucous membranes.

The presence of a mixed infestation should be established before treatment.
The presence of a mixed infestation with ectoparasites not indicated on the labelling should be established before treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Irritation, sensitization, and adverse effects on the neuronal system might occur.
Avoid contact with skin, eyes and mucous membranes, and oral uptake.
Wear protective gloves.
Change heavily contaminated clothes and wash before re-use.
Do not eat, drink or smoke while using this veterinary medicinal product.
In case of skin contact, wash the exposed parts thoroughly with water and soap.
In case of contact with eyes, immediately rinse thoroughly with water.
People with known hypersensitivity to this veterinary medicinal product should avoid contact with the veterinary medicinal product.
If you feel unwell after the use of this veterinary medicinal product seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
The long-term effects of the VMP on the population dynamics of dung beetles have not been investigated; therefore, it is advisable not to treat animals on the same pasture every season.

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation..

Interaction with other medicinal products and other forms of interaction:
In combination with organo-phosphorous substances, the toxicity of deltamethrin is enhanced. Therefore, it is not advisable to use such products in combination with this veterinary medicinal product.

Overdose:
Deltamethrin is of very low toxicity when administered topically as an aqueous suspension. Therefore, acute toxicity through transdermal absorption is not expected.
Overdoses of three times the recommended dose did not induce any adverse effects in cattle. An accidental oral intake of a large quantity or the existence of extensive skin lesions can lead to signs of

toxicity such as salivation, excitement, clonic convulsions and paresthesias. A veterinarian should be consulted. The therapy has to be symptomatic and supportive.

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

7. Adverse events

Cattle, sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Skin irritation (such as erythema, pruritus) Restlessness, hyperactivity, anxiety, behavioural disorder* Hypersensitivity

* Tossing heads and tails

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: {national system details}

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

Pour-on use. Shake well before use.
Pour on the product evenly along the backline of the animals from the base of head to the tail.

Flies:
Cattle
Up to 100 kg bodyweight: 10 ml
100 to 300 kg bodyweight: 20 ml
More than 300 kg bodyweight: 30 ml

Sucking and biting lice as well as sheep keds:
Cattle, Sheep
10 ml per animal

9. Advice on correct administration

The following points have to be considered for the treatment of sheep:
- treat shortly after shearing (animals with short fleece)
- keep shorn group away from non-shorn animals
- shear and treat ewes 4-6 weeks before parturition

The veterinary medicinal product is administered as a single treatment.
Treatment against flies can be repeated every 6-10 weeks, depending on the infestation degree.
The duration of control for *Musca* spp. may vary.
The influence of weather on the duration of efficacy has not been investigated.

10. Withdrawal periods

Cattle:
Meat and offal: 18 days
Milk: 0 days

Sheep:
Meat and offal: 1 day

Milk: 12 hours

11. Special storage precautions

Keep out of the sight and reach of children.

Do not refrigerate or freeze. Protect from frost.

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

Shelf life after first opening the immediate packaging: 30 weeks

12. Special precautions for disposal

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

This veterinary medicinal product should not enter water courses as deltamethrin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{to be adapted nationally}

Pack sizes: 250 ml, 1000 ml bottle with screw-on applicator and 2500 ml bottle packed with an applicator gun to be tube-connected to the bottle.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/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 contact details to report suspected adverse reactions>:
{to be adapted nationally}

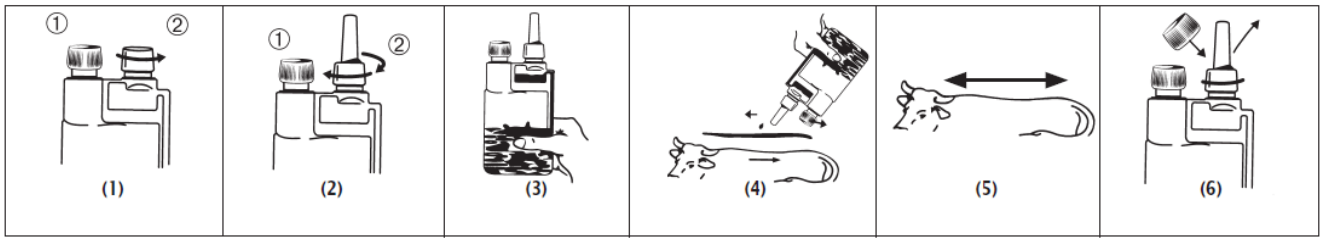
Manufacturer responsible for batch release:
Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

<Local representatives <and contact details to report suspected adverse reactions>:>
{to be adapted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{to be adapted nationally}>

17. Other information

Use of the dosing system (applicable for the 250 ml and the 1 000ml presentation):



1) Remove cap no. 2 from the dose reservoir of the bottle. Keep cap no. 1 closed at all times.
2) Attach the applicator to the dose reservoir.
3) Fill the dose reservoir by squeezing the container.
4) Hold the container on the applicator side. After inverting the bottle and during application ensure that the applicator is kept below the dose reservoir (see above diagram). Apply the dose by pouring it along the animal's spine from the base of the base of the head to the tail, while pressing lightly on the container. (Repeat the procedure to treat flies on animals weighing more than 100 kg who need a larger than 10 ml dose).
5) Application area for this veterinary medicinal product: Ensure that the complete dose has been applied to the animal's back.
6) When all the animals have been treated, remove the applicator before recapping the bottle.
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