

**<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>  
{NATURE/TYPE} COMBINED LABEL AND PACKAGE LEAFLET FOR SINGLE  
LANGUAGE PACKS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Topimec 5 mg/ml Pour-on Solution  
Ivermectin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Ivermectin 5 mg/ml

**3. PHARMACEUTICAL FORM**

A clear pour-on solution

**4. PACKAGE SIZE**

250ml, 500ml, 1L, 2.5L & 5L.

**5. TARGET SPECIES**

Cattle (beef and non-lactating dairy cattle)

**6. INDICATION(S)**

For the treatment of infections with gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle. For further information see outer carton.

## **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For single topical administration.

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dose of 500 micrograms/kg bodyweight).

Read the carton before use.

## **8. WITHDRAWAL PERIOD**

Meat and offal: 28 days

Milk: Not permitted for use in lactating cattle producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days prior to calving.

## **9. SPECIAL WARNING(S), IF NECESSARY**

Read the carton before use.

If irritation persists, seek medical advice and show the label to the doctor.

## **10. EXPIRY DATE**

EXP

## **11. SPECIAL STORAGE CONDITIONS**

Store upright in tightly closed original container and box when not in use.

HIGHLY FLAMMABLE – keep away from heat, sparks, open flame or other sources of ignition. Protect from light. Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

Read the carton before use.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

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

Marketing authorisation holder:  
Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ

Manufacturer responsible for batch release:  
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 11990/4061

**17. MANUFACTURER’S BATCH NUMBER**

BN:

**18. OTHER INFORMATION**

250 ml, 500 ml, 1 L, 2.5 L and 5 L

Not all pack sizes may be marketed.

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>  
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>  
{NATURE/TYPE} Carton for single language packs

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Topimec 5 mg/ml Pour-on Solution  
Ivermectin

**2. STATEMENT OF ACTIVE SUBSTANCES**

A clear pour-on solution containing Ivermectin 5 mg/ml

**3. PHARMACEUTICAL FORM**

A clear pour on solution

**4. PACKAGE SIZE**

250ml, 500ml, 1L, 2.5L, 5L & 6L

**5. TARGET SPECIES**

Cattle (beef and non-lactating dairy cattle)

**6. INDICATION(S)**

For the treatment and control of infections with gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle as shown below:

**Gastro-intestinal roundworms** (adults and fourth stage larvae): *Ostertagia ostertagi* including inhibited larvae, *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp., *Oesophagostomum radiatum* and *Strongyloides papillosus* (adult only).

**Lungworms** (adult and fourth stage larvae): *Dictyocaulus viviparus*

**Eye worms (adult):** *Thelazia* spp

**Warbles (parasitic stages):** *Hypoderma bovis* and *Hypoderma lineatum*

**Mange Mites:** *Chorioptes bovis* and *Sarcoptes scabiei* var *bovis*

**Lice:** *Linognathus vituli*, *Haematopinus eurysternus* and *Damalinea bovis*

The product given at the recommended dose rate of 500 micrograms/kg bodyweight has persistent activity against *Trichostrongylus axei* and *Cooperia* spp. acquired during the 14 days after treatment; only if the whole herd is treated simultaneously, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment; *Dictyocaulus viviparus* acquired during the first 28 days after treatment. It also has a persistent activity against horn flies (*Haematobia irritans*) for 28 days after treatment, partial efficacy may last for up to 35 days post application. Occasionally variable activity may be observed against *Haemonchus placei* (L4), *Cooperia* spp, *Trichostrongylus axei* and *Trichostrongylus colubriformis*.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

The formulation should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

<b><u>Bodyweight</u></b> <b><u>(kg)</u></b>	<b><u>Dose</u></b> <b><u>Volume</u></b> <b><u>(ml)</u></b>	<b><u>Doses</u></b> <b><u>per</u></b> <b><u>250ml</u></b> <b><u>Pack</u></b>	<b><u>Doses</u></b> <b><u>per</u></b> <b><u>500ml</u></b> <b><u>Pack</u></b>	<b><u>Doses</u></b> <b><u>per 1</u></b> <b><u>Litre</u></b> <b><u>Pack</u></b>	<b><u>Doses</u></b> <b><u>per</u></b> <b><u>2.5</u></b> <b><u>Litre</u></b> <b><u>Pack</u></b>	<b><u>Doses</u></b> <b><u>per 5</u></b> <b><u>Litre</u></b> <b><u>Pack</u></b>	<b><u>Doses</u></b> <b><u>per 6</u></b> <b><u>Litre</u></b> <b><u>Pack</u></b>
Up to 100	10	25	50	100	250	500	600
101 – 150	15	16	33	66	166	333	400
151 – 200	20	12	25	50	125	250	300
201 – 250	25	10	20	40	100	200	240
251 – 300	30	8	16	33	83	166	200

**Dosage:** 1 ml per 10 kg bodyweight (based on the recommended dose of 500 micrograms/kg bodyweight).

Over 300 kg bodyweight, give 5ml per 50 kg bodyweight

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

If animals are to be treated collectively rather than individually they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over- dosing.

The product should be used with appropriate dosing equipment. The interval between two treatments should be at least 28 days.

## **8. WITHDRAWAL PERIOD**

Meat and offal: 28 days

Milk: Not permitted for use in lactating cattle producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days prior to calving.

## **9. SPECIAL WARNING(S), IF NECESSARY**

### Special precautions for use in animals

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin has been reported in *Cooperia spp.* and in *Ostertagia ostertagi* in cattle. Resistance has also been reported in *Haemonchus contortus* in cattle outside the EU. Therefore, the use of this product should be based on local (region, farm) epidemiological information about susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

Ivermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

Occasionally slight irritation at the application site may occur. However, usually these irritations rapidly disappear without treatment.

No sign of toxicity appeared up to 1.5 mg/kg (3 times the recommended dose rate). No antidote has been identified. The signs of overdose can be trembling, convulsions and coma. In case of overdose symptomatic treatment should be given

To avoid secondary reactions due to death of *Hypoderma* larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of the period of warble fly activity and before the larvae reach their resting site.

Do not treat cattle when hair or hide is wet. Do not treat cattle if rain is expected, as rain within two hours of treatment may reduce efficacy. However, the efficacy of the product against established infections of *O. ostertagi* or *D. viviparus* is not adversely affected if the hide is wet or if rain falls shortly after treatment. Do not apply to areas of skin that may have mange scabs or other lesions or to areas contaminated with mud or manure.

The influence of extreme climatic conditions on persistent activity of the product is unknown. The product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

### User warnings

The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use.

As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water. If irritation persists, seek medical advice and show the package label to the doctor. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention.

Use only in well-ventilated areas or outdoors.

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

Wash hands after use.

For external use only.

### Use during pregnancy and lactation

The product can be used during pregnancy and lactation.

The product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

### **Adverse reactions:**

If you notice any side effects, even those not already listed on this carton or you think that the medicine has not worked, please inform your veterinary surgeon.

### **Contra-indications:**

Do not use in cases of known hypersensitivity to the active ingredient.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

<b>10. EXPIRY DATE</b>
------------------------

EXP

**11. SPECIAL STORAGE CONDITIONS**

Store upright in tightly closed original container and box when not in use.

Precautions: HIGHLY FLAMMABLE – keep away from heat, sparks, open flame or other sources of ignition. Protect from light. Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

EXTREMELY DANGEROUS FOR FISH AND AQUATIC ORGANISMS. Do not contaminate ponds, waterways or ditches with the product or empty containers.

Any unused veterinary medicinal products or waste materials 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.

**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 AND THE MANUFACTURING AUTHORITISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:  
Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ

Manufacturer responsible for batch release:  
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 11990/4061

**17. MANUFACTURER'S BATCH NUMBER**

BN:

**18. OTHER INFORMATION**

250 ml, 500 ml, 1 L, 2.5 L, 5 L and 6 L

Not all pack sizes may be marketed.

**<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>  
{NATURE/TYPE} LABEL FOR MULTI-LANGUAGE PACKS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Topimec 5 mg/ml Pour-on Solution  
Ivermectin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Ivermectin 5 mg/ml

**3. PHARMACEUTICAL FORM**

A clear pour-on solution

**4. PACKAGE SIZE**

250ml, 500ml, 1L, 2.5L & 5L.

**5. TARGET SPECIES**

Cattle (beef and non-lactating dairy cattle)

**6. INDICATION(S)**

For the treatment of infections with gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle. For further information see pack leaflet.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For single topical administration.

Dosage: 1 ml per 10 kg bodyweight (based on a recommended dose of 500 micrograms/kg bodyweight).

Read the pack leaflet before use.

## **8. WITHDRAWAL PERIOD**

Meat and offal: 28 days

Milk: Not permitted for use in lactating cattle producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days prior to calving.

## **9. SPECIAL WARNING(S), IF NECESSARY**

Read the pack leaflet before use.

If irritation persists, seek medical advice and show the label to the doctor.

## **10. EXPIRY DATE**

EXP

## **11. SPECIAL STORAGE CONDITIONS**

Store upright in tightly closed original container and box when not in use.

HIGHLY FLAMMABLE – keep away from heat, sparks, open flame or other sources of ignition. Protect from light. Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

Read the pack leaflet before use.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Chanelle Animal Health Ltd  
7 Rodney Street  
Liverpool  
L1 9HZ

**16. MARKETING AUTHORISATION NUMBER(S)**

VM 11990/4061

**17. MANUFACTURER’S BATCH NUMBER**

BN:

**18. OTHER INFORMATION**

**<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>**  
**<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>**  
**{NATURE/TYPE} Carton for Multi-language packs**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Topimec 5 mg/ml Pour-on Solution  
Ivermectin

**2. STATEMENT OF ACTIVE SUBSTANCES**

A clear pour-on solution containing Ivermectin 5 mg/ml

**3. PHARMACEUTICAL FORM**

A clear pour on solution

**4. PACKAGE SIZE**

250ml, 500ml, 1L, 2.5L, 5L & 6L

**5. TARGET SPECIES**

Cattle (beef and non-lactating dairy cattle)

**6. INDICATION(S)**

For the treatment and control of gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle. For further information see pack leaflet.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For single topical administration.

**Dosage:** 1 ml per 10 kg bodyweight (based on the recommended dose of 500 micrograms/kg bodyweight).

Read the pack leaflet before use.

#### **8. WITHDRAWAL PERIOD**

Meat and offal: 28 days

Milk: Not permitted for use in lactating cattle producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days prior to calving.

#### **9. SPECIAL WARNING(S), IF NECESSARY**

Read the pack leaflet before use.

#### **10. EXPIRY DATE**

EXP

#### **11. SPECIAL STORAGE CONDITIONS**

Store upright in tightly closed original container and box when not in use.

Precautions: HIGHLY FLAMMABLE – keep away from heat, sparks, open flame or other sources of ignition. Protect from light. Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

Read the pack leaflet before use.

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

For animal treatment 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**

Chanelle Animal Health Ltd  
7 Rodney Street  
Liverpool  
L1 9HZ

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 11990/4061

**17. MANUFACTURER’S BATCH NUMBER**

BN:

**18. OTHER INFORMATION**

**B. PACKAGE LEAFLET FOR MULTI-LANGUAGE PACKS**

**PACKAGE LEAFLET:**  
Topimec 5 mg/ml Pour-on Solution

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

Marketing authorisation holder:  
Chanelle Animal Health Ltd  
7 Rodney Street  
Liverpool  
L1 9HZ

Manufacturer responsible for batch release:  
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Topimec 5 mg/ml Pour-on Solution  
Ivermectin

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

A clear pour on solution

**4. INDICATION(S)**

For the treatment and control of gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites and sucking and biting lice of beef and non-lactating dairy cattle as shown below:

**Gastro-intestinal roundworms** (adults and fourth stage larvae): *Ostertagia ostertagi* including inhibited larvae, *Haemonchus placei*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Cooperia* spp., *Oesophagostomum radiatum* and *Strongyloides papillosus* (adult only).

**Lungworms** (adult and fourth stage larvae): *Dictyocaulus viviparus*

**Eye worms (adult):** *Thelazia* spp

**Warbles (parasitic stages):** *Hypoderma bovis* and *Hypoderma lineatum*

**Mange Mites:** *Chorioptes bovis* and *Sarcoptes scabiei* var *bovis*

**Lice:** *Linognathus vituli*, *Haematopinus eurysternus* and *Damalinia bovis*

The product given at the recommended dose rate of 500 micrograms/kg bodyweight has persistent activity against *Trichostrongylus axei* and *Cooperia* spp. acquired during the 14 days after treatment; only if the whole herd is treated simultaneously, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment; *Dictyocaulus viviparus* acquired during the first 28 days after treatment. It also has a persistent activity against horn flies (*Haematobia irritans*) for 28 days after treatment, partial efficacy may last for up to 35 days post application. Occasionally variable activity may be observed against *Haemonchus placei* (L4), *Cooperia* spp, *Trichostrongylus axei* and *Trichostrongylus colubriformis*.

## **5. CONTRAINDICATIONS**

Do not use in cases of known hypersensitivity to the active ingredient.

The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

## **6. ADVERSE REACTIONS**

If you notice any side effects, even those not already listed on this carton or you think that the medicine has not worked, please inform your veterinary surgeon.

Occasionally slight irritation at the application site may occur. However, usually these irritations rapidly disappear without treatment.

## **7. TARGET SPECIES**

Cattle (beef and non-lactating dairy cattle)

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

The formulation should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

<u>Bodyweight</u> <u>(kg)</u>	<u>Dose</u> <u>Volume</u> <u>(ml)</u>	<u>Doses</u> <u>per</u> <u>250ml</u> <u>Pack</u>	<u>Doses</u> <u>per</u> <u>500ml</u> <u>Pack</u>	<u>Doses</u> <u>per 1</u> <u>Litre</u> <u>Pack</u>	<u>Doses</u> <u>per</u> <u>2.5</u> <u>Litre</u> <u>Pack</u>	<u>Doses</u> <u>per 5</u> <u>Litre</u> <u>Pack</u>	<u>Doses</u> <u>per 6</u> <u>Litre</u> <u>Pack</u>
Up to 100	10	25	50	100	250	500	600
101 – 150	15	16	33	66	166	333	400
151 – 200	20	12	25	50	125	250	300
201 – 250	25	10	20	40	100	200	240
251 – 300	30	8	16	33	83	166	200

**Dosage:** 1 ml per 10 kg bodyweight (based on the recommended dose of 500 micrograms/kg bodyweight).

Over 300 kg bodyweight, give 5ml per 50 kg bodyweight

## 9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

If animals are to be treated collectively rather than individually they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over- dosing.

The product should be used with appropriate dosing equipment. The interval between two treatments should be at least 28 days.

## 10. WITHDRAWAL PERIOD(S)

Meat and offal: 28 days

Milk: Not permitted for use in lactating cattle producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days prior to calving.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Store upright in tightly closed original container and box when not in use.

Precautions: HIGHLY FLAMMABLE – keep away from heat, sparks, open flame or other sources of ignition. Protect from light. Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNING(S)

### Special precautions for use in animals

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin has been reported in *Cooperia spp.* and in *Ostertagia ostertagi* in cattle. Resistance has also been reported in *Haemonchus contortus* in cattle outside the EU. Therefore, the use of this product should be based on local (region, farm) epidemiological information about susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

Ivermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

No sign of toxicity appeared up to 1.5 mg/kg (3 times the recommended dose rate). No antidote has been identified. The signs of overdose can be trembling, convulsions and coma. In case of overdose symptomatic treatment should be given

To avoid secondary reactions due to death of *Hypoderma* larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of the period of warble fly activity and before the larvae reach their resting site.

Do not treat cattle when hair or hide is wet. Do not treat cattle if rain is expected, as rain within two hours of treatment may reduce efficacy. However, the efficacy of the product against established infections of *O. ostertagi* or *D. viviparus* is not adversely affected if the hide is wet or if rain falls shortly after treatment. Do not apply to areas of skin that may have mange scabs or other lesions or to areas contaminated with mud or manure.

The influence of extreme climatic conditions on persistent activity of the product is unknown. The product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

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

The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use.

As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water. If irritation persists, seek medical advice and show the package label to the doctor. If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention.

Use only in well-ventilated areas or outdoors.

**HIGHLY FLAMMABLE.**

Keep away from heat, spark, open flame or other source of ignition.

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

Wash hands after use.

For external use only.

Pregnancy and lactation

The product can be used during pregnancy and lactation.

The product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

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

EXTREMELY DANGEROUS FOR FISH AND AQUATIC ORGANISMS. Do not contaminate ponds, waterways or ditches with the product or empty containers.

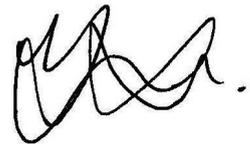
Any unused veterinary medicinal products or waste materials should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

250 ml, 500 ml, 1 L, 2.5 L, 5 L and 6 L

Not all pack sizes may be marketed.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 12 April 2022