<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{NATURE/TYPE} Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Premadex 0.5% w/v Pour-on Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear pour-on solution containing Ivermectin 0.5% w/v

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment 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, Strongyloides papillosus* (adult).
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.*

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.

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

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

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 *Ostertagia ostertagi* in cattle. 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.

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. As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

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 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.

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.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Close container when not in use. Store upright in the original box when not in use.
Precautions: HIGHLY FLAMMABLE – keep away from heat, sparks, open flame or other sources of ignition. Protect from light.

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 ditches with the product or empty container.
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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd.
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom

Manufactured by:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4039

17. MANUFACTURER'S BATCH NUMBER

BN:

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE} Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Premadex 0.5% w/v Pour-on Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear pour-on solution containing Ivermectin 0.5%w/v

3. PHARMACEUTICAL FORM

Pour on solution

4. PACKAGE SIZE

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

5. TARGET SPECIES

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 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, Strongyloides papillosus* (adult).
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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.

Bodyweight (kg)	Dose Volume (ml)	Doses per 250ml Pack	Doses per 500ml Pack	Doses per 1 Litre Pack	Doses per 2.5 Litre Pack	Doses per 5 Litre Pack	Doses per 6 Litre Pack
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

Over 300 kg bodyweight, give 5ml per 50 kg bodyweight
Dosage: 1 ml per 10 kg bodyweight (based on the recommended dose of 500 micrograms/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

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 *Ostertagia ostertagi* in cattle. 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. As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

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10. EXPIRY DATE

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11. SPECIAL STORAGE CONDITIONS

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For animal treatment only.

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd.
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom

Manufactured by:
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16. MARKETING AUTHORISATION NUMBER

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17. MANUFACTURER'S BATCH NUMBER

BN:

18. OTHER INFORMATION

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.

Approved: 01 May 2018