LABELLING AND PACKAGE LEAFLET

LABEL – 1L, 2.5L and 10L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Premadex 0.8mg/ml Oral Solution for Sheep

Ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Each ml contains:

Ivermectin	0.8mg

Excipient(s):

Benzyl Alcohol (E1519)	28.6mg
Butylhydroxyanisole (E320)	0.10 mg
Propyl Gallate (E310)	0.10 mg

3. PHARMACEUTICAL FORM

Oral Solution
A transparent, yellow coloured solution.

4. PACKAGE SIZE

1 litre, 2.5 litre and 10 litre

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the treatment of infections with the following parasites:
Nematodes
Gastrointestinal roundworms (adult and fourth larval stage)
Haemonchus contortus
Teladorsagia circumcincta
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Including *N. battus*
Strongyloides papillosus
Chabertia ovina

Lungworms(adult and fourth larval stage)
Dictyocaulus filaria
Arthropods
Nasal bot (all larval stages)
Oestrus ovis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The veterinary medicinal product should be given orally, The recommended dose rate is 0.2 mg ivermectin per kg bodyweight (corresponding to 2.5 ml per 10 kg bodyweight).

The following table shows the actual dose to be given and the number of animals of differing bodyweights which can be dosed from this pack:

Weight Range (kg)	Dose Volume (ml)	Doses per 1 L Pack	Doses per 2.5 L Pack	Doses per 10 L Pack
Up to 10	2.5	400	1000	4000
11-20	5.0	200	500	2000
21-30	7.5	133	333	1333
31-40	10.0	100	250	1000
41-50	12.5	80	200	800
51-60	15.0	67	166	666

Over 60 kg give 2.5 ml per 10 kg bodyweight
1 Litre Treats 80 x 50kg Sheep
200 x 20kg lamb

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

8. WITHDRAWAL PERIOD

Meat & Offal: 10 days.

Milk: Do not use in lactating sheep producing milk for human consumption. Sheep must not be treated within 60 days prior to the commencement of lactation, if milk is to be used for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications
Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

Special precautions for use in animals

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.
Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing. Veterinary advice should also be sought if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved.
Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.

Adverse Reactions
Some sheep may cough immediately after treatment. This passing response is of no consequence.
If you notice any serious effects or other effects not mentioned in this label, please inform your veterinary surgeon.

User Safety
Wash hands after use. Avoid contact with skin and eyes.
Do not eat, drink or smoke while handling the product.
Wear impervious gloves when handling or administering the product.
As absorption through skin can occur, in the event of accidental skin contact, wash the affected area immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water.

Use during pregnancy, lactation or lay
The veterinary medicinal product can be administered to ewes at any stage of pregnancy or lactation.

Overdose (symptoms, emergency procedures, antidotes), if necessary
At doses up to 4 mg ivermectin per kg administered by stomach tube (20x the recommended dose level) undesirable toxic reactions occurred. Acute symptoms (ataxia, staggering gait, incoordination, depression) were observed at the dose rate of 8 mg/kg (40x the recommended dose level) during a study carried out on 4 animals. Twenty-four hours later, the animals showed only mild incoordination and depression.
Three days post dose all the animals were nearly normal. It is possible that the signs of toxaemia were due to the propylene glycol.
No antidote has been identified. Symptomatic treatment may be beneficial.

Special warnings for each target species
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 weigh or misadministration of the product.

Resistance to ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU and it is common in *Haemonchus* in sheep outside the EU. Therefore the use of this product should be based on local (regional, farm)

epidemiological information about susceptibility of nematode and recommendations on how to limit further selection for resistance to anthelmintics.

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

Interaction with other medicinal products and other forms of interaction
None known.

10. EXPIRY DATE

<EXP {month/year}>
Shelf life after first opening the container: 18 months.
Once opened, use by .....

11. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
Do not contaminate surface waters or ditches with product or used container.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

For animal treatment only
<To be supplied only on veterinary prescription> (include where required)

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder and manufacturer for the batch release:

Chanelle Pharmaceutical Manufacturing Limited,
Loughrea,
Co. Galway,
Ireland.

16. MARKETING AUTHORISATION NUMBER

Vm 08749/4029

17. MANUFACTURER'S BATCH NUMBER

Legal category LM Licensed Merchant (IE)
<BN> {number}

LABEL – 5L, 6L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Premadex 0.8mg/ml Oral Solution for Sheep
Ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Each ml contains:

Ivermectin	0.8mg

Excipient(s):

Benzyl Alcohol (E1519)	28.6mg
Butylhydroxyanisole (E320)	0.10 mg
Propyl Gallate (E310)	0.10 mg

3. PHARMACEUTICAL FORM

Oral Solution
A transparent, yellow coloured solution.

4. PACKAGE SIZE

5 litre and 6 litre (5+1)

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the treatment of infections with the following parasites:
Nematodes
Gastrointestinal roundworms (adult and fourth larval stage)
Haemonchus contortus
Teladorsagia circumcincta
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Including *N. battus*
Strongyloides papillosus
Chabertia ovina

Lungworms(adult and fourth larval stage)
Dictyocaulus filaria

Arthropods
Nasal bot (all larval stages)
Oestrus ovis

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The veterinary medicinal product should be given orally. The recommended dose rate is 0.2 mg ivermectin per kg bodyweight (corresponding to 2.5 ml per 10 kg bodyweight).
The following table shows the actual dose to be given and the number of animals of differing bodyweights which can be dosed from this pack:

Weight Range (kg)	Dose Volume (ml)	Doses per 5 L Pack
Up to 10	2.5	2000
11-20	5.0	1000
21-30	7.5	666
31-40	10.0	500
41-50	12.5	400
51-60	15.0	333

Over 60 kg give 2.5 ml per 10 kg bodyweight
5 Litre Treats 400 x 50kg Sheep
1000 x 20kg lamb

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

8. WITHDRAWAL PERIOD

Meat & Offal: 10 days.
Milk: Do not use in lactating sheep producing milk for human consumption. Sheep must not be treated within 60 days prior to the commencement of lactation, if milk is to be used for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications
Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

Special precautions for use in animals
The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.
Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing. Veterinary advice should also be sought if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved'.

Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.

Adverse Reactions
Some sheep may cough immediately after treatment. This passing response is of no consequence.
If you notice any serious effects or other effects not mentioned in this label, please inform your veterinary surgeon.

User Safety
Wash hands after use. Avoid contact with skin and eyes.
Do not eat, drink or smoke while handling the product.
Wear impervious gloves when handling or administering the product.
As absorption through skin can occur, in the event of accidental skin contact, wash the affected area immediately with soap and water.
If accidental eye exposure occurs, flush the eyes immediately with water.

Use during pregnancy, lactation or lay
The veterinary medicinal product can be administered to ewes at any stage of pregnancy or lactation.

Overdose (symptoms, emergency procedures, antidotes), if necessary
At doses up to 4 mg ivermectin per kg administered by stomach tube (20x the recommended dose level) undesirable toxic reactions occurred. Acute symptoms (ataxia, staggering gait, incoordination, depression) were observed at the dose rate of 8 mg/kg (40x the recommended dose level) during a study carried out on 4 animals. Twenty-four hours later, the animals showed only mild incoordination and depression.
Three days post dose all the animals were nearly normal. It is possible that the signs of toxaemia were due to the propylene glycol.
No antidote has been identified. Symptomatic treatment may be beneficial.

Special warnings for each target species
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 or misadministration of the product.

Resistance to ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU and it is common in *Haemonchus* in sheep outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematode and recommendations on how to limit further selection for resistance to anthelmintics.
Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Fecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, and anthelmintic belonging to another pharmacological class and having different mode of action should be used.
There is cross-resistance with other avermectins and with milbemycins.

Interaction with other medicinal products and other forms of interaction
None known.

10. EXPIRY DATE

<EXP {month/year}>
Shelf life after first opening the container: 18 months.
Once opened, use by .....

11. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
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14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

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17. MANUFACTURER'S BATCH NUMBER

Legal category LM Licensed Merchant (IE)
<BN> {number}

Carton 5L and 6L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Topimec 0.8mg/ml Oral Solution for Sheep
Premadex 0.8mg/ml Oral Solution for Sheep (UK)
Ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Each ml contains:

Ivermectin	0.8mg

Excipient(s):

Benzyl Alcohol (E1519)	28.6mg
Butylhydroxyanisole (E320)	0.10 mg
Propyl Gallate (E310)	0.10mg

3. PHARMACEUTICAL FORM

Oral Solution
A transparent, yellow coloured solution

4. PACKAGE SIZE

5 litre and 6 litre (5+1)

5. TARGET SPECIES

Sheep

6. INDICATION(S)

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Nematodes
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Milk: Do not use in lactating sheep producing milk for human consumption. Sheep must not be treated within 60 days prior to the commencement of lactation, if milk is to be used for human consumption.

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There is cross-resistance with other avermectins and with milbemycins.

Interaction with other medicinal products and other forms of interaction
None known.

10. EXPIRY DATE

<EXP {month/year}>
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Once opened, use by _____

11. SPECIAL STORAGE CONDITIONS

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Legal category LM Licensed Merchant (IE)
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Approved: 21 June 2018