PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (5 Litre label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oramec Drench
(ivermectin)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

ORAMEC Drench is a pale yellow free-flowing solution containing 0.8 mg/ml ivermectin.
Preservative: Benzyl Alcohol 31 mg/ml.

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

5 Litre.

5. TARGET SPECIES

Sheep.

6. INDICATIONS

For the treatment and control of:
• Adult and immature gut roundworms including *Nematodirus* spp.
• Inhibited larval stages of *Haemonchus contortus* and *Teladorsagia circumcincta*
• Strains of *Haemonchus contortus* and *Teladorsagiacircumcincta* resistant to benzimidazole-based white drenches
• Adult and immature lungworms
• Nasal bots

7. METHOD AND ROUTE OF ADMINISTRATION

DIRECTIONS FOR USE
Use the enclosed universal spouted cap to connect your standard drenching gun to the flexipack containing ORAMEC.

DOSAGE AND ADMINISTRATION
ORAMEC Drench for Sheep should be given orally at the recommended dosage level of 2.5 ml per 10 kg bodyweight (corresponding to the recommended dose rate of 0.2 mg ivermectin per kg bodyweight).

Weight Range (kg)	Dose Volume (ml)	Doses per 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 (corresponding to the recommended dose rate of 0.2 mg ivermectin per kg bodyweight).

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Do not mix with other products.

8. WITHDRAWAL PERIOD

Meat and offal: 6 days.
Do not use in lactating animals producing milk for human consumption. If milk is to be used for human consumption animals should not be treated within 60 days prior to the commencement of lactation.

9. SPECIAL WARNINGS, IF NECESSARY

CONTRA-INDICATIONS, WARNINGS, ETC.

User warnings: Do not smoke, eat or drink while handling the product.
Wash hands after use. Avoid contact with skin and eyes.
Wear impervious gloves when handling or administering the product. As absorption through the skin can occur, in case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

Some animals may cough slightly immediately after treatment.

The product has been formulated specifically for use in sheep. Do not use in other species, as severe adverse reactions, including fatalities in dogs, may occur.

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 macrocyclic lactones (which includes ivermectin) has been reported in *Teladorsagia* spp. in sheep within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from direct sunlight.

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

CONTAINER DISPOSAL
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
Do not contaminate surface waters or ditches with the product or used containers.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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 *[Distribution category]*

For animal treatment only.

POM-VPS

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4191

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

5 Litre Flexipack
Comfortable and easy to use
Empties with minimal waste

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (2.5 Litre label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oramec Drench
(ivermectin)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

ORAMEC Drench is a pale yellow free-flowing solution containing 0.8 mg/ml ivermectin.
Preservative: Benzyl Alcohol 31 mg/ml.

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

2.5 Litre.

5. TARGET SPECIES

Sheep.

6. INDICATIONS

For the treatment and control of:
• Adult and immature gut roundworms including *Nematodirus* spp.
• Inhibited larval stages of *Haemonchus contortus* and *Teladorsagia circumcincta*
• Strains of *Haemonchus contortus* and *Teladorsagia circumcincta* resistant to benzimidazole-based white drenches
• Adult and immature lungworms
• Nasal bots

7. METHOD AND ROUTE OF ADMINISTRATION

DIRECTIONS FOR USE
Use the enclosed universal spouted cap to connect your standard drenching gun to the flexipack containing ORAMEC.

DOSAGE AND ADMINISTRATION
ORAMEC Drench for Sheep should be given orally at the recommended dosage level of 2.5 ml per 10 kg bodyweight (corresponding to the recommended dose rate of 0.2 mg ivermectin per kg bodyweight).

Weight Range (kg)	Dose Volume (ml)	Doses per Pack
Up to 10	2.5	1000
11-20	5.0	500
21-30	7.5	333
31-40	10.0	250
41-50	12.5	200
51-60	15.0	166

Over 60 kg give 2.5 ml per 10 kg bodyweight (corresponding to the recommended dose rate of 0.2 mg ivermectin per kg bodyweight).

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Do not mix with other products.

8. WITHDRAWAL PERIOD

Meat and offal: 6 days.
Do not use in lactating animals producing milk for human consumption. If milk is to be used for human consumption animals should not be treated within 60 days prior to the commencement of lactation.

9. SPECIAL WARNINGS, IF NECESSARY

CONTRA-INDICATIONS, WARNINGS, ETC.

User warnings: Do not smoke, eat or drink while handling the product.
Wash hands after use. Avoid contact with skin and eyes.
Wear impervious gloves when handling or administering the product. As absorption through the skin can occur, in case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

Some animals may cough slightly immediately after treatment.

The product has been formulated specifically for use in sheep. Do not use in other species, as severe adverse reactions, including fatalities in dogs, may occur.
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 macrocyclic lactones (which includes ivermectin) has been reported in *Teladorsagia* spp. in sheep within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from direct sunlight.

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

CONTAINER DISPOSAL
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
Do not contaminate surface waters or ditches with the product or used containers.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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 *[Distribution category]*

For animal treatment only.

POM-VPS

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4191

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

2.5 Litre Flexipack
Comfortable and easy to use
Empties with minimal waste

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE WHERE THERE IS NO PACKAGE LEAFLET (1 Litre label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oramec Drench
(ivermectin)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

ORAMEC Drench is a pale yellow free-flowing solution containing 0.8 mg/ml ivermectin.
Preservative: Benzyl Alcohol 31 mg/ml.

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

1 Litre.

5. TARGET SPECIES

Sheep.

6. INDICATIONS

For the treatment and control of:
:
• Adult and immature gut roundworms including *Nematodirus* spp.
• Inhibited larval stages of *Haemonchus contortus* and *Teladorsagia circumcincta*
• Strains of *Haemonchus contortus* and *Teladorsagia circumcincta*
resistant to benzimidazole-based white drenches
• Adult and immature lungworms
• Nasal bots

7. METHOD AND ROUTE OF ADMINISTRATION

DOSAGE AND ADMINISTRATION
ORAMEC Drench for Sheep should be given orally at the recommended dosage level of 2.5 ml per 10 kg bodyweight (corresponding to the recommended dose rate of 0.2 mg ivermectin per kg bodyweight).

Weight Range (kg)	Dose Volume (ml)	Doses per Pack
Up to 10	2.5	400
11-20	5.0	200
21-30	7.5	133
31-40	10.0	100
41-50	12.5	80
51-60	15.0	66

Over 60 kg give 2.5 ml per 10 kg bodyweight (corresponding to the recommended dose rate of 0.2 mg ivermectin per kg bodyweight).
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Do not mix with other products.

8. WITHDRAWAL PERIOD

Meat and offal: 6 days.
Do not use in lactating animals producing milk for human consumption. If milk is to be used for human consumption animals should not be treated within 60 days prior to the commencement of lactation.

9. SPECIAL WARNINGS, IF NECESSARY

CONTRA-INDICATIONS, WARNINGS, ETC.

User warnings: Do not smoke, eat or drink while handling the product.
Wash hands after use. Avoid contact with skin and eyes.
Wear impervious gloves when handling or administering the product. As absorption through the skin can occur, in case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

Some animals may cough slightly immediately after treatment.

The product has been formulated specifically for use in sheep. Do not use in other species, as severe adverse reactions, including fatalities in dogs, may occur.
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 macrocyclic lactones (which includes ivermectin) has been reported in *Teladorsagia* spp. in sheep within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from direct sunlight.
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.

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

CONTAINER DISPOSAL
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.
Do not contaminate surface waters or ditches with the product or used containers.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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 *[Distribution category]*

For animal treatment only.

POM-VPS

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:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Batch release site:
Boehringer Ingelheim Animal Health France SCS4 Chemin du Calquet,
31000 TOULOUSE
France

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4191

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

1 litre, 2.5 litre and 5 litre high density polyethylene backpacks and 1 litre high density polyethylene jerrycans.
Not all pack sizes may be marketed.

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET (5 litre carton)

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

Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Batch release site:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet,
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oramec Drench
(ivermectin)

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

ORAMEC Drench is a pale yellow free-flowing solution containing 0.8 mg/ml ivermectin.
Preservative: Benzyl Alcohol 31 mg/ml.

4. PHARMACEUTICAL FORM

Oral solution.

5. PACKAGE SIZE

5 litre

6. INDICATIONS

For the treatment and control of:
• Adult and immature gut roundworms including *Nematodirus* spp.
• Inhibited larval stages of *Haemonchus contortus* and *Teladorsagia circumcincta*
• Strains of *Haemonchus contortus* and *Teladorsagia circumcincta* resistant to benzimidazole-based white drenches
• Adult and immature lungworms
• Nasal bots of sheep

ORAMEC provides outstanding control of the important internal parasites of sheep.
• ORAMEC kills adult and immature gut roundworms including *Nematodirus* spp.

• ORAMEC kills inhibited larval stages of *Haemonchus contortus* and *Teladorsagiacircumcincta*
• ORAMEC kills strains of *Haemonchus contortus* and *Teladorsagia circumcincta* that are resistant to
benzimidazole-based white drenches
• ORAMEC kills adult and immature lungworms
• ORAMEC kills nasal bots of sheep

The product provides effective control against the following parasites of sheep:
Gastro-intestinal roundworms (adult and immature):
Haemonchus contortus, Teladorsagia circumcincta, Trichostrongylus spp., *Cooperia* spp., *Nematodirus* spp., including *N. battus, Strongyloides papillosus, Oesophagostomum* spp., *Chabertia ovina* (Adults). Inhibited larval stages, benzimidazole resistant strains of *H. contortus* and *T. circumcincta* are also controlled.

Lungworms (adult and immature): *Dictyocaulus filaria*

Nasal bot (all larval stages): *Oestrus ovis*

7. CONTRAINDICATIONS

The product has been formulated specifically for use in sheep. Do not use in other species, as severe adverse reactions, including fatalities in dogs, may occur.

8. ADVERSE REACTIONS

Some animals may cough slightly immediately after treatment.

9. TARGET SPECIES

Sheep.

10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

DIRECTIONS FOR USE
Use the enclosed universal spouted cap in this pack to connect your standard drenching gun to the flexipack containing ORAMEC Drench.

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

Do not mix with other products.

DOSAGE AND ADMINISTRATION
ORAMEC Drench for Sheep should be given orally at the recommended dosage level of 2.5 ml per 10 kg bodyweight (corresponding to the recommended dose rate of 0.2 mg ivermectin per 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 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 (corresponding to the recommended dose rate of 0.2 mg ivermectin per kg bodyweight).

Ewes may be treated at any stage of pregnancy.

11. ADVICE ON CORRECT ADMINISTRATION

Get the most out of ORAMEC
To get the best results it is essential to use ORAMEC Drench correctly and to ensure that the proper dose is given.

12. WITHDRAWAL PERIOD

Meat and offal: 6 days.
Do not use in lactating animals producing milk for human consumption. If milk is to be used for human consumption animals should not be treated within 60 days prior to the commencement of lactation.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from direct sunlight.
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.

14. SPECIAL WARNINGS

User warnings: Do not smoke, eat or drink while handling the product.
Wash hands after use.
Avoid contact with skin and eyes.
Wear impervious gloves when handling or administering the product. As absorption through the skin can occur, in case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

No interactions have been observed.

OVERDOSE
The product has demonstrated a wide safety margin at the recommended dose level. The product may be used in sheep of all ages. During a study to assess toxicological effects only mild incoordination and depression were observed at 20 x the recommended dose level (4 mg ivermectin per kg bodyweight, administered by stomach tube). At 40 x the recommended dose level (8 mg ivermectin per kg bodyweight, also administered by stomach tube) acute symptoms (ataxia, staggering gait, incoordination and depression) were observed. Within 24 hours nearly all animals appeared normal and within 3 days all animals appeared clinically normal. No antidote has been identified, however, symptomatic treatment may be beneficial.

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 macrocyclic lactones (which includes ivermectin) has been reported in *Teladorsagia* spp. in sheep within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

15. EXPIRY DATE

Expiry date:

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

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

For animal treatment only.

POM-VPS

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

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER

Vm 08327/4191

21. MANUFACTURER’S BATCH NUMBER

Batch No.:

22. OTHER INFORMATION

To be supplied only on veterinary prescription.

5 litre Flexipack
Comfortable and easy to use - Empties with minimal waste
Treats 400 x 50 kg sheep or 1000 x 20 kg lambs.

1 litre, 2.5 litre and 5 litre high density polyethylene backpacks and 1 litre high density polyethylene jerrycans.
Not all pack sizes may be marketed.

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET (2.5 litre carton)

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

Marketing Authorisation Holder:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Batch release site:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet,
31000 Toulouse
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oramec Drench
(ivermectin)

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

ORAMEC Drench is a pale yellow free-flowing solution containing 0.8 mg/ml ivermectin.
Preservative: Benzyl Alcohol 31 mg/ml.

4. PHARMACEUTICAL FORM

Oral solution.

5. PACKAGE SIZE

2.5 litre

6. INDICATIONS

For the treatment and control of:
• Adult and immature gut roundworms including *Nematodirus* spp.
• Inhibited larval stages of *Haemonchus contortus* and *Teladorsagia circumcincta*
• Strains of *Haemonchus contortus* and *Teladorsagia circumcincta* resistant to benzimidazole-based white drenches
• Adult and immature lungworms
• Nasal bots of sheep

ORAMEC provides outstanding control of the important internal parasites of sheep.
• ORAMEC kills adult and immature gut roundworms including *Nematodirus* spp.

• ORAMEC kills inhibited larval stages of *Haemonchus contortus* and *Teladorsagiacircumcincta*
• ORAMEC kills strains of *Haemonchus contortus* and *Teladorsagia circumcincta* that are resistant to
benzimidazole-based white drenches
• ORAMEC kills adult and immature lungworms
• ORAMEC kills nasal bots of sheep

The product provides effective control against the following parasites of sheep:
Gastro-intestinal roundworms (adult and immature):
Haemonchus contortus, Teladorsagia circumcincta, Trichostrongylus spp., *Cooperia* spp., *Nematodirus* spp., including *N. battus, Strongyloides papillosus, Oesophagostomum* spp., *Chabertia ovina* (Adults). Inhibited larval stages, benzimidazole resistant strains of *H. contortus* and *T. circumcincta* are also controlled.

Lungworms (adult and immature): *Dictyocaulus filaria*

Nasal bot (all larval stages): *Oestrus ovis*

7. CONTRAINDICATIONS

The product has been formulated specifically for use in sheep. Do not use in other species, as severe adverse reactions, including fatalities in dogs, may occur.

8. ADVERSE REACTIONS

Some animals may cough slightly immediately after treatment.

9. TARGET SPECIES

Sheep.

10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

DIRECTIONS FOR USE
Use the enclosed universal spouted cap in this pack to connect your standard drenching gun to the flexipack containing ORAMEC Drench.

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

Do not mix with other products.

DOSAGE AND ADMINISTRATION
ORAMEC Drench for Sheep should be given orally at the recommended dosage level of 2.5 ml per 10 kg bodyweight (corresponding to the recommended dose rate of 0.2 mg ivermectin per 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 Pack
Up to 10	2.5	1000
11-20	5.0	500
21-30	7.5	333
31-40	10.0	250
41-50	12.5	200
51-60	15.0	166

Over 60 kg give 2.5 ml per 10 kg bodyweight (corresponding to the recommended dose rate of 0.2 mg ivermectin per kg bodyweight).

Ewes may be treated at any stage of pregnancy.

11. ADVICE ON CORRECT ADMINISTRATION

Get the most out of ORAMEC
To get the best results it is essential to use ORAMEC Drench correctly and to ensure that the proper dose is given.

12. WITHDRAWAL PERIOD

Meat and offal: 6 days.
Do not use in lactating animals producing milk for human consumption. If milk is to be used for human consumption animals should not be treated within 60 days prior to the commencement of lactation.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from direct sunlight.
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.

14. SPECIAL WARNINGS

User warnings: Do not smoke, eat or drink while handling the product.
Wash hands after use.
Avoid contact with skin and eyes.
Wear impervious gloves when handling or administering the product. As absorption through the skin can occur, in case of accidental spillage onto the skin or eyes, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

No interactions have been observed.

OVERDOSE
The product has demonstrated a wide safety margin at the recommended dose level. The product may be used in sheep of all ages. During a study to assess toxicological effects only mild incoordination and depression were observed at 20 x the recommended dose level (4 mg ivermectin per kg bodyweight, administered by stomach tube). At 40 x the recommended dose level (8 mg ivermectin per kg bodyweight, also administered by stomach tube) acute symptoms (ataxia, staggering gait, incoordination and depression) were observed. Within 24 hours nearly all animals appeared normal and within 3 days all animals appeared clinically normal. No antidote has been identified, however, symptomatic treatment may be beneficial.

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 macrocyclic lactones (which includes ivermectin) has been reported in *Teladorsagia* spp. in sheep within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

15. EXPIRY DATE

Expiry date:

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

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED .

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-VPS

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER

Vm 08327/4191

21. MANUFACTURER'S BATCH NUMBER

Batch No.:

22. OTHER INFORMATION

To be supplied only on veterinary prescription.

2.5 litre Flexipack
Comfortable and easy to use - Empties with minimal waste
Treats 200 x 50 kg sheep or 500 x 20 kg lambs

1 litre, 2.5 litre and 5 litre high density polyethylene backpacks and 1 litre high density polyethylene jerrycans.
Not all pack sizes may be marketed.

Approved 28 May 2020