PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depidex Drench 0.08% w/v Drench Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A free-flowing aqueous solution containing 0.08% w/v ivermectin.

Group 3ML

3. PHARMACEUTICAL FORM

Oral Solution.

4. PACKAGE SIZE

1.0L, 2.5L, 5.0L

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

Front carton text:

For the treatment and control of:

- Adult and immature gut roundworms including *Nematodirus* spp and
- Adult and immature lungworms of sheep
- Inhibited larval stages of *Haemonchus contortus* and *Ostertagia circumcincta* in sheep
- Strains of *Haemonchus contortus* and *Ostertagia circumcincta* resistant to benzimidazole-based white drenches in sheep
- Nasal bots in sheep

Back carton text:

Depidex Drench Drench provides control of the important internal parasites of sheep

- Depidex Drench treats and controls adult and immature gut roundworms including *Nematodirus* species in sheep

- Depidex Drench treats and controls inhibited larval stages of *Haemonchus contortus* and *Ostertagia circumcincta* in sheep
- Depidex Drench treats and controls strains of *Haemonchus contortus* and *Ostertagia circumcincta* that are resistant to benzimidazole-based white drenches in sheep
- Depidex Drench treats and controls adult and immature lungworms in sheep
- Depidex Drench treats and controls nasal bots in sheep

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 (if any).

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 tests(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 (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 nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Depidex Drench should be given orally at the recommended dosage level of 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 Pack
Up to 10	2.5	according to pack size
11 - 20	5.0	as presented on label
21 - 30	7.5	
31 - 40	10.0	
41 - 50	12.5	

51 - 60	15.0

Over 60 kg bodyweight give 2.5 ml per 10 kg bodyweight. It is recommended that a suitably calibrated dosing gun is used to allow accurate dosing especially in young animals.

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

Sheep must not be slaughtered for human consumption until 14 days after last treatment. Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not smoke, drink or eat while handling the product. Avoid contact with skin and eyes. In case of accidental eye or skin contact, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

Wash hands after use. Some animals may cough slightly immediately after treatment. This is a temporary occurrence and of no clinical consequence. Depidex Drench has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Protect from light.

Do not store above 25°C.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, surface waters or ditches with the product or empty container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

To be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Animal Health

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 12051/4110

17. MANUFACTURER’S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depidex Drench 0.08% w/v Drench Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Depidex Drench is a free-flowing solution containing 0.08% w/v ivermectin.

3. PHARMACEUTICAL FORM

Oral Solution.

4. PACKAGE SIZE

1.0L, 2.5L, 5.0L

5. TARGET SPECIES

Sheep.

6. INDICATION(S)

Front Label text:

For the treatment and control of:

- Adult and immature gut roundworms including *Nematodirus* spp and
- Adult and immature lungworms of sheep
- Inhibited larval stages of *Haemonchus contortus* and *Ostertagia circumcincta* in sheep
- Strains of *Haemonchus contortus* and *Ostertagia circumcincta* resistant to benzimidazole-based white drenches in sheep
- Nasal bots in sheep

Back Label Text

Depidex Drench provides control of the important internal parasites of sheep.

For the treatment and control of: adult and immature gut roundworms including *Nematodirus* spp and adult and immature lungworms; inhibited larval stages of *Haemonchus contortus* and *Ostertagia circumcincta*; strains of *Haemonchus contortus* and *Ostertagia circumcincta* resistant to benzimidazole-based white drenches and nasal bots in sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Depidex Drench should be given orally at the recommended dosage level of 2.5 ml per 10 kg bodyweight. Estimate bodyweight accurately prior to dosing. 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 (1l)
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

Weight Range (kg)	Dose Volume (ml)	Doses per Pack (2.5l)
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

Weight Range (kg)	Dose Volume (ml)	Doses per Pack (5l)
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. It is recommended that a suitably calibrated dosing gun is used to allow accurate dosing especially in young animals.

Do not mix with other products.

8. WITHDRAWAL PERIOD

Sheep must not be slaughtered for human consumption until 14 days after last treatment. Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not smoke, drink or eat while handling the product. Avoid contact with skin and eyes. In case of accidental eye or skin contact, wash the affected area with clean running water immediately. Seek medical attention if irritation persists.

Wash hands after use.

Some animals may cough slightly immediately after treatment. This is a temporary occurrence and is of no clinical consequence.

Depidex Drench has been formulated specifically for use in sheep. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

IMPORTANT: READ CARTON TEXT BEFORE USE

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, surface waters and ditches with the product or empty container. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

To be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Novartis Animal Health

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 12501/4110

17. MANUFACTURER'S BATCH NUMBER

Approved: 09/01/2018