SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depidex Drench 0.08% w/v oral solution for sheep

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Active ingredients

Ivermectin	0.08% w/v

Excipients

Benzyl Alcohol	3.0% v/v as antimicrobial preservative.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution
A pale yellow clear liquid

4. CLINICAL PARTICULARS

4.1. Target species

Sheep

4.2. Indications for use specifying target species

The treatment and control of gastrointestinal nematodes, lungworms and nasal bots of sheep.

Sheep: Gastrointestinal worms (adult and immature):
Haemonchus contortus, Ostertagia circumcincta, Trichostrongylus spp, *Cooperia* spp, *Nematodirus* spp including *N. battus, Strongyloides papillosus, Oesophagostomum* spp, and adult *Chabertia ovina*

Inhibited larval stages and benzimidazole resistant strains of *H.contortus* and *Ostertagia circumcincta* are also controlled.

Lungworms (adult and immature):
Dictyocaulus filaria

Nasal bot (all larval stages):
Oestrus ovis

4.3. Contraindications

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

The product is not for intravenous or intramuscular use.

4.4. 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, 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 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 (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.

4.5. Special precautions for use

i. Special precautions for use in animals

None known.

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

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.

4.6. Adverse reactions (frequency and seriousness)

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

4.7. Use during pregnancy, lactation or lay

The product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption.

4.8. Interaction with other medicaments and other forms of interaction

None

4.9. Amounts to be administered and administration route

Do not mix with other products.
Ivermectin should be administered orally at 200µg/kg bodyweight (2.5ml per 10 kg bodyweight).
To ensure administration of correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

4.10. Overdose (symptoms, emergency procedures and antidotes)

No antidote has been identified; however symptomatic treatment may be beneficial.

4.11. Withdrawal periods

Sheep may not be slaughtered for human consumption until 14 days after the last treatment.

Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiparasitic

ATC vet code: QP54AA01

5.1. Pharmacodynamic properties

Ivermectin belongs to the avermectin (3-AV) class of anthelmintic compounds, chemical group of anthelmintic 3-AV.

Ivermectin is a 22, 23-dihydro derivative of an avermectin (which is a fermentation product produced by *Streptomyces avermitilis*) and consists of two homologues: B1a and B1b. it is a highly effective parasiticide with nematocidal, insecticidal and acaracidal activity documented in a wide range of domesticated animals.

Avermectins interact with glutamate-gated chloride ion channels, to increase membrane permeability to chloride ions, causing irreversible neuromuscular blockade in nematodes, followed by paralysis and death.

5.2. Pharmacokinetic particulars

Depidex Drench was administered orally to sheep at a dose of 200 µg/kg. Maximum plasma concentration was 5.99 µg/ml at 16.2 hours after administration and the elimination half-life was approximately 25 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 Excipients

Benzyl alcohol

6.2 Incompatibilities

None known.

6.3. Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 5 years

6.4. Special precautions for storage

Do not store above 25°C. Protect from light.

6.5. Nature and Composition of Immediate Packaging

2.5lt and 5.0lt volumes, presented in white high density polyethylene Jerry Cans, sealed with white polypropylene screw caps. Or white high density polyethylene back-packs, sealed with white polypropylene screw caps.
Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused medicinal product or waste materials if any

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.

Do not contaminate ponds, waterways or ditches with the product or used container.

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

7. MARKETING AUTHORISATION HOLDER

Novartis Animal Health UK Limited
Frimley Business Park
Frimley
Camberley
Surrey
GU16 7SR

8. MARKETING AUTHORISATION NUMBER

Vm 12501/4110

9. DATE OF FIRST AUTHORISATION

19th September 2001

10. DATE OF REVISION OF TEXT

June 2010