Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ORAMEC Drench for Sheep 0.8 mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Ivermectin	0.8 mg/ml

Excipients	
Benzyl Alcohol	31.0 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep.

4.2 Indications for use, specifying the target species

ORAMEC Drench for Sheep is highly effective for the treatment and control of mixed infections with the following gastrointestinal roundworms (including benzimidazole-resistant strains of *Haemonchus contortus*, *Ostertagia circumcincta*and levamisole-resistant strains of *H. contortus, O. circumcincta*and *T. colubriformis*):

Gastrointestinal roundworms(adult and fourth larval stage)
*Haemonchus contortus**
*Ostertagia circumcincta**
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Including*N. battus*
Strongyloides papillosus
Oesophagostomum spp.
Chabertia ovina

Lungworms(adult and fourth larval stage)
Dictyocaulus filaria

Nasal bot(all larval stages)
Oestrus ovis
* including benzimidazole resistant strains.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

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 bodyweight, 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 tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals:
No special precautions are required.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
Do not smoke or eat while handling the product.
Avoid contact with skin and eyes. If this occurs, rinse affected area immediately with water.

4.6 Adverse reactions (frequency and seriousness)

ORAMEC Drench for Sheep is readily accepted by the animal. Some sheep may cough immediately after treatment. This passing response is of no consequence.

4.7 Use during pregnancy, lactation or lay

ORAMEC Drench for Sheep can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not used for human consumption. ORAMEC Drench for Sheep will not affect the fertility of breeding ewes and rams and can be given to all ages of animals including young lambs.

4.8 Interaction with other medicinal products and other forms of interactions

ORAMEC Drench for Sheep may be used concurrently with clostridial vaccine without any adverse effects. Adequate vaccination of sheep against clostridial infections is strongly recommended.

4.9 Amounts to be administered and administration route

Oral administration with a dosing gun of 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, bodyweight 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 overdosing.
Use properly calibrated dosing equipment.
ORAMEC Drench for Sheep has demonstrated a wide safety margin at the recommended dose level. ORAMEC Drench for Sheep may be used in sheep of all ages.

4.10 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; however, symptomatic treatment may be beneficial.

4.11 Withdrawal period(s)

Animals intended for human consumption must not be slaughtered during treatment.

Animals intended for human consumption may only be slaughtered from 6 days after the last treatment.
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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Anthelmintics, ivermectin.
ATCvet code: QP54AA01

5.1 Pharmacodynamic properties

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).
The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic particulars

Maximum plasma concentration:
The maximum plasma concentration is reached in 6 hours after oral administration and ranges from 12 to 34 ng/ml at the dose rate of 0.3 mg ivermectin per kg bodyweight. This concentration gradually decreases to range from 2 to 7 ng/ml 2 days post dose.
Excretion: length of time and route:
A liquid chromatographic method with fluorescence detection indicates that after oral administration of 0.3 mg ivermectin per kg bodyweight, the liver (target tissue) has average residues ranging from 72 ppb at 1 day post dose to 8 ppb at 7 days post dose. At early time periods fat had higher residues than liver. By 5 days post dose the liver and fat residues were equivalent. Fat averaged 145 ppb at 1 day, declining to 9 ppb at 7 days. Muscle and kidney had lower residues at all withdrawal time periods studied.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Polysorbate 80
Benzyl Alcohol
Disodium Phosphate Dodecahydrate
Sodium Dihydrogen Phosphate Dihydrate
Purified Water

6.2 Major incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The product is packaged in polyethylene backpacks containing 1 litre, 2.5 litres and 5 litres, and in polyethylene jerrycans containing 1 litre.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations. Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Do not contaminate lakes and streams with unused product or waste material as free ivermectin may adversely affect fish and certain water borne organisms.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/072/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1994
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

July 2018