1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORAMEC Drench for Sheep 0.8 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Ivermectin 0.8 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol	31.0 mg
Propylene Glycol	
Polysorbate 80	
Disodium Phosphate Dodecahydrate	
Sodium Dihydrogen Phosphate Dihydrate	
Purified Water	

Pale yellow free-flowing solution.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

The veterinary medicinal product 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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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 veterinary medical product.
Avoid contact with skin and eyes. If this occurs, rince affected area immediately with water.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cough[1]

[1] immediately after treatment. This passing respose is of no consequence.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation provided that the milk is not used for human consumption.

Fertility:
The veterinary medicinal product will not affect the fertility of breeding ewes and rams and can be given to all ages of animals including young lambs.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product may be used concurrently with clostridial vaccine without any adverse effects. Adequate vaccination of sheep against clostridial infections is strongly recommended.

3.9 Administration routes and dosage

Oral use.
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 a correct dose, body weight 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.
The use of suitably calibrated measuring equipment is recommended. The veterinary medical product has demonstrated a wide safety margin at the recommended dose level. The veterinary medical product may be used in sheep of all ages.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 6 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medical 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.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/072/001

8. DATE OF FIRST AUTHORISATION

01 October 1994

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

27 January 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).