SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORAMEC Drench (ivermectin)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Ingredient: Ivermectin 0.8mg
Excipients: Preservative: Benzyl Alcohol 31 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution.
Clean, clear, slightly yellow liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep.

4.2 Indications for use, specifying the target species

The product is indicated for the treatment and control of gastro-intestinal nematodes, lungworms and nasal bots of sheep. The product at the recommended dose rate of 200 mcg ivermectin per kg bodyweight provides effective control against the following parasites of sheep:

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

4.3 Contra-indications

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.

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 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.

4.5 Special precautions for use

i. Special precautions for use in animals

No special precautions are required.

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

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.

4.6 Adverse reactions (frequency and seriousness)

Some sheep may cough immediately after treatment. This passing response is of no consequence.

4.7 Use during pregnancy, lactation or lay

Ewes may be treated at any stage of pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions have been observed.

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). The dosing gun should be calibrated sufficiently accurately to ensure precise dosing of young sheep.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal periods

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.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Ivermectin is a member of the macrocyclic lactone class of endectocides.

ATC Vet Code: QP54AA01

5.1 Pharmacodynamic properties

Mechanism of Action
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 properties

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.
At the dose rate of 0.3 mg ivermectin per kg bodyweight, the half-life of the product is 1.9 days in the liver and 3 days in the fat.

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 the liver (target tissue) had 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

Benzyl alcohol

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

1 litre, 2.5 litre and 5 litre high density polyethylene backpacks, and 1 litre high density polyethylene jerrycans. The backpacks are closed with a high density polyethylene (screw fit) cap with an induction seal, and the jerricans are closed with a low density polyethylene (screw fit) cap.

Not all pack sizes may be marketed.

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

Container disposal:
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters 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

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/5071

9. DATE OF FIRST AUTHORISATION

23 February 1994

10. DATE OF REVISION OF THE TEXT

September 2025

ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable.

Gavin Hall
Approved: 04 September 2025