ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET
1 litre, 2,5 litre and 5 litre packs
Package leaflet information will be printed on the immediate packaging

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

Manufacturer responsible for Batch Release:
Bimeda Animal Health Limited,
2/3/4 Airton Close,
Tallaght,
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimamec 5mg/mL Pour-on solution for Cattle, Ivermectin

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Ivermectin 5 mg/ml

4. PHARMACEUTICAL FORM

Pour-on solution

5. PACKAGE SIZE

1 L
2,5 L
5 L

6. INDICATION(S)

For the treatment and control of gastro-intestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef and non-lactating dairy cattle.

The product at the recommended dosage level of 500 µg ivermectin per kg bodyweight effectively controls the following parasites of cattle:

Gastrointestinal roundworms (adult and fourth stage larvae):
Ostertagia ostertagi
(including inhibited stage)
Haemonchus placei
Trichostrongylus axei T. colubriformis Cooperia spp. *Oesophagostomum radiatum*
Strongyloides papillosus adult
Trichuris spp. adult

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp.

Warbles (parasitic stages):
Hypoderma bovis
H. lineatum

Mites:
Sarcoptes scabiei var. bovis
Chorioptes bovis

Lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Damalinia bovis

Bimamec 5mg/mL Pour-on solution for Cattle given at the recommended dosage of 500 micrograms per kg bodyweight, controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment and *Dictyocaulus viviparus* (lungworm) acquired during the first 28 days after treatment. It also controls horn fly (*Haematobia irritans*) for up to 35 days after treatment.

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.
Rainfall before or after treatment does not affect the efficacy of Bimamec 5mg/mL Pour-on solution for Cattle.

7. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
The product has been formulated for topical application specifically in cattle.
Do not apply or administer to other species as severe adverse reactions, including fatalities in dogs, may occur.

Do not apply to areas of skin which have mange, scabs or other lesions or to areas contaminated with mud or manure.

8. ADVERSE REACTIONS

Undesirable effects are not expected when the product is used at the recommended dose rate..

9. TARGET SPECIES

Cattle

10. DOSAGE FOR EACH SPECIES, ROUTE(S) OF ADMINISTARTION

For pour-on use.
Dosage: 1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 micrograms per kg bodyweight).
Administration: The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.
The product should be used with appropriate dosing equipment. To ensure administration of correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

11. ADVICE ON CORRECT ADMINISTRATION

The product should be applied using an appropriate application device.

12. WITHDRAWAL PERIODS

Withdrawal period(s):
Meat and offal: 15 days.
Do not use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

13. SPECIAL STORAGE PRECAUTIONS

Flammable - keep away from heat, sparks, open flame or other sources of ignition.
Bottles should remain upright during storage.
Cloudiness may result when the product is stored at temperatures below 0°C. Allowing the product to warm at room temperature will restore the normal appearance without affecting efficacy.

14. SPECIAL WARNING(S)

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 *Cooperia* spp. and *Ostertagia ostertagi* in cattle within the EU. Therefore, the use of this and other similar macrocyclic lactone products 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.

Bimamec 5mg/mL Pour-on solution for Cattle has been formulated for topical application specifically in cattle. It should not be applied or administered to other species, as severe adverse reactions, including fatalities in dogs, may occur. Avoid extremes of temperature and protect from light.

Special precautions for use in animals
For external use only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
HIGHLY FLAMMABLE - KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME OR OTHER SOURCES OF IGNITION.
The product may be irritating to human skin and eyes and the users should be careful not to apply it to themselves or others. Operators should wear rubber gloves and boots with a waterproof coat when
applying the product. Protective clothing should be washed after use.
Use only in well-ventilated areas or outdoors.
As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water. If irritation persists, seek medical advice and show the package leaflet or label to the physician.
If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Wash hands after use.
Do not smoke, eat or drink while handling the product.

Other precautions
This product is very toxic to aquatic organisms, sediment dwelling organisms, and dung insects. Long-term effects on dung insects caused by continuous or repeated use cannot be excluded.

Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of this product and other products of the same anthelmintic class. Therefore, the repetition of treatment in a pasture during a season should be performed only in the absence of alternative treatment and on veterinary advice.

Pregnancy, lactation or lay:
The product can be administered to beef cows at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

Interaction with other medicinal products and other forms of interaction:
The product may be used concurrently with foot and mouth disease vaccine or clostridial vaccine.

Overdose (symptoms, emergency procedures, antidotes):
No sign of toxicity appeared up to 5 mg/kg (10 times the recommended dose rate).
No antidote has been identified.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTEMATERIALS, IF ANY

EXTREMELY DANGEROUS TO AQUATIC ORGANISMS AND DUNG FAUNA. Do not contaminate surface waters or ditches with product or used container. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

January 2024

17. OTHER INFORMATION

Available in 1 L, 2.5 L and 5 L pack size.
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. THE WORDS 'FOR ANIMAL TREATMENT ONLY'AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-VPS

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

Keep out of the sight and reach of children.

20. EXPIRY DATE

<EXP {month/year}>

21. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/4044

22. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot>

Approved 02 January 2024