ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON (50ml, 250ml, 500ml & 3 x 500ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Plus 10 mg/ml + 100 mg/ml Solution for Injection
for Cattle
Ivermectin,Clorsulon

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains
Active substance:

Clorsulon	100 mg
Ivermectin	10 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50ml
250ml
500ml
3 x 500ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment of mixed infestations with adult liver fluke (*Fasciola hepatica*) and gastro-intestinal roundworms, lungworms, eye worms, warbles, mites, or sucking lice of cattle. See package leaflet for full list of indicated parasite species and life stages.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Dosage: 1ml per 50 kg bodyweight by subcutaneous injection under the loose skin in front of, or behind the shoulder.

To ensure administration of the correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 66 days.
Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached use within 28 days.
Once broached, use by / /

11. SPECIAL STORAGE CONDITIONS

Protect from light.
Keep the container in the outer carton in order to protect from light.
Discard unused material.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
Unit 2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/4038

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL – 250ml/500ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Plus 10 mg/ml + 100 mg/ml Solution for Injection
for Cattle
Ivermectin,Clorsulon

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains
Active substance:

Clorsulon	100 mg
Ivermectin	10 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

250ml
500ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment of mixed infestations with adult liver fluke (*Fasciola hepatica*) and gastro-intestinal roundworms, lungworms, eye worms, warbles, mites or sucking lice of cattle. See package leaflet for full list of indicated parasite species and life stages.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Dosage: 1ml per 50 kg bodyweight (based on a dosage level of 200 mcg ivermectin plus 2 mg clorsulon per kg bodyweight) by subcutaneous injection under the loose skin in front of, or behind the shoulder.

To ensure administration of the correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 66 days.
Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached use within 28 days.
Once broached, use by / /

11. SPECIAL STORAGE CONDITIONS

Protect from light.
Keep the container in the outer carton in order to protect from light.
Discard unused material.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Cross Vetpharm Limited,
Broomhill Road,
Tallaght,
Dublin 24,
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4038

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL – 50ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Plus 10 mg/ml + 100 mg/ml Solution for Injection for Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains
Active substance:

Clorsulon	100 mg
Ivermectin	10 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous injection

5. WITHDRAWAL PERIOD(S)

Meat and offal: 66 days.
Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

EXP:
Once broached use within 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Maximec Plus 10 mg/ml + 100 mg/ml Solution for Injection for Cattle.

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

Bimeda Animal Health Limited
Unit 2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maximec Plus 10 mg/ml + 100 mg/ml Solution for Injection for Cattle
Ivermectin,Clorsulon

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

1 ml contains 10 mg of ivermectin and 100 mg of clorsulon.

4. INDICATION(S)

For the treatment of mixed infestations with **adult liver fluke** (*Fasciola hepatica*) and nematodes or arthropods of the following parasite species and life stage:

Nematodes:
Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia ostertagi (including inhibited larval stages)
O. lyrata
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata
C. pectinata
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
N. spathiger (adult)
Trichuris spp. (adult)
Lungworms (adult and fourth-stage larvae):
Dictyocaulus viviparus
Eye worms (adult):
Thelazia spp.

Arthropods:
Warbles (parasitic stages):
Hypoderma bovis
H. lineatum
Mange mites:
Psoroptes bovis
Sarcoptes scabiei var. *bovis*
Sucking lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

This product may also be used as an aid in the control of biting lice *(Damalinia bovis)* and the mange mite *Chorioptes bovis,* but complete elimination may not occur.

Persistent Activity
This product given at the recommended dosage of 0.2 mg per kg bodyweight controls re-infection with *Haemonchus placei, Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment; *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 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.

5. CONTRAINDICATIONS

Do not use intramuscularly or intravenously.
This product is a low volume product authorised for use in cattle.
The product must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur. Some dog breeds (Collies, Old English Sheepdogs and related breeds or crosses) are at particular risk of severe adverse reactions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions disappeared without treatment.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The product should be administered only by subcutaneous injection under the loose skin in front of, or behind the shoulder.

The recommended dosage is 200 µg ivermectin and 2 mg clorsulon per kg bodyweight corresponding to a single dose of 1 ml per 50 kg bodyweight. Divide doses greater than 10 ml between two injection sites.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, to avoid under- or over-dosing, they should be grouped according to their bodyweight and dosed accordingly.

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.

Use of a sterile 17 gauge ½ inch (15 - 20 mm) needle is recommended. Replace with a fresh sterile needle after every 10-12 animals or sooner if the needle becomes soiled.

When the temperature of the product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15°C will greatly increase the ease with which the product can be injected.

When using the 250 ml and 500 ml pack sizes, use only automatic syringe equipment.
For the 50 ml pack sizes, use of a multidose syringe is recommended.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 66 days.
Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Protect from light.
Keep the container in the outer carton in order to protect from light.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

Do not use this veterinary medicinal product after the expiry date which is stated on the outer carton after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:

For use only in beef cattle and non-lactating dairy cattle.

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 (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 Ostertagia ostertagi and Cooperia species in cattle within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of these helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for use in animals
This product does not contain any antimicrobial preservative.
Swab septum before removing each dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause eye and skin irritation.
Avoid contact with skin or eyes.
In case of skin or eye contact, wash exposed area with plenty of clean water. If symptoms persist, seek medical advice.
Do not eat or smoke while handling the product.
Take care to avoid accidental self-injection: the product may cause local irritation and/or pain at the site of injection.
In case of accidental self-injection, seek immediate medical advice and show the information leaflet or the label to the physician.
Wash hands after use.

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

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of ivermectin and products of the same anthelmintic class in cattle, sheep and pigs.
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.

Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment.

Environmental properties
Like other macrocyclic lactones, ivermectin has the potential to adversely affect non-target organisms. Faeces containing ivermectin excreted onto pasture by treated animals may reduce the abundance feeding organisms which may impact on the dung degradation.

Use during pregnancy, lactation, lay:
Can be used in pregnancy and lactation.
Can be used in breeding animals.
Please also refer to ‘Withdrawal Periods’.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
A dose of 25ml product per 50kg bodyweight (25 times the recommended dose level) may result in an injection site lesion, including tissue necrosis, oedema, fibrosis and inflammation. No other drug-related reactions have been observed.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2024

15. OTHER INFORMATION

Commercial presentations:
Box of 1 HDPE bottle of 50ml, 250ml, 500ml and 3 x 500ml

Not all presentations may be marketed.

Vm 50146/4038

Approved: 09 May 2024