A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{NATURE/TYPE} Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec 10 mg/ml solution for injection for Cattle and Pigs
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Ivermectin 10 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml, 250 ml, 500 ml

5. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle) and Pigs

6. INDICATION(S)

For OTC products

Cattle: Treatment of infections with gastro-intestinal roundworms, lungworms, warbles, mange mites and lice at a dose rate of 1 ml per 50 kg (based on a recommended dosage level of 200 mcg ivermectin per kg b.w.). The volume administered per injection site should not exceed 10 ml.

Inject subcutaneously in front or behind the shoulder using aseptic techniques

Pigs:Treatment of infections with gastro-intestinal roundworms, lungworms, mange mites and lice at a dose rate of 1 ml per 33 kg (based on a recommended dosage level of 300 mcg ivermectin per kg b.w.)
For piglets weighing less than 16 kg give 0.1 ml per 3 kg
Inject subcutaneously into the neck using aseptic techniques

This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle
Meat and offal: 49 days.
Do not use in lactating cows producing milk for human consumption. Do not use in cattle producing milk for human consumption or in dairy cows within 60 days prior to calving.

Pigs
Meat and offal: 28 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Shelf-life after first opening the immediate packaging: 28 days.

Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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 product 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 containers.

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

For animal treatment only.

LM Licensed Merchant

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

Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool, L19HZ, United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4023

17. MANUFACTURER'S BATCH NUMBER

BN:

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{NATURE/TYPE} Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec 10 mg/ml solution for injection for Cattle and Pigs
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Ivermectin 10 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml, 250 ml, 500ml

5. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle) and Pigs

6. INDICATION(S)

For OTC products
Cattle: Treatment of infections with gastro-intestinal roundworms, lungworms, warbles, mange mites and lice at a dose rate of 1 ml per 50 kg (based on a recommended dosage level of 200 mcg ivermectin per kg b.w.). The volume administered per injection site should not exceed 10 ml.
Inject subcutaneously in front or behind the shoulder using aseptic techniques.

Pigs: Treatment of infections with gastro-intestinal roundworms, lungworms, mange mites and lice at a dose rate of 1 ml per 33 kg (based on a recommended dosage level of 300 mcg ivermectin per kg b.w.).
For piglets weighing less than 16 kg give 0.1 ml per 3 kg.
Inject subcutaneously into the neck using aseptic techniques.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Inject subcutaneously using aseptic techniques.
Assess bodyweight as accurately as possible before calculating the dose.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle
Meat and offal: 49 days.
Do not use in lactating cows producing milk for human consumption. Do not use in cattle producing milk for human consumption or in dairy cows within 60 days prior to calving.

Pigs
Meat and offal: 28 days.

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer by the intravenous or intramuscular route. Do not use in animals with known hypersensitivity to the active ingredient. The product has been formulated specifically for use in cattle and pigs only. Do not use in dogs or cats.
The product may cause local irritation and/or pain at the site of injection. Take care to avoid self administration.
Do not smoke or eat while handling the product.
Wash hands after use.

The product is very toxic to aquatic organisms and dung insects.

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

Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Shelf-life after first opening the immediate packaging: 28 days.

Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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

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 product should be disposed of in accordance with local requirements.

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

For animal treatment only.

LM Licensed Merchant

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

Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool, L19HZ, United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4023

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

Package leaflet

Animec 10 mg/ml solution for injection for Cattle and Pigs
Ivermectin

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

Marketing authorisation holder: Chanelle Animal Health Ltd., 7 Rodney Street, Liverpool L19 HZ, UK.

Manufacturer responsible for the batch release: Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland
and
Labiana Life Sciences S.A., Venus 26, Can Parellada Industrial, 08228 Terrassa Barcelona Spain.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanimec 10 mg/ml solution for injection (in Ireland)
Ivermectin.

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

Each ml contains:
Active substance:
Ivermectin 10 mg
The product is a clear, colourless to slightly yellow solution.

4. INDICATION(S)

Cattle: Treatment of infections with gastro-intestinal roundworms, lungworms, warbles, mange mites and lice as shown below:
Gastro-intestinal Roundworms (adult and fourth stage larvae):
Ostertagia spp (including inhibited O. *ostertagi)*, *Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia* spp, *Oesophagostomum radiatum, Nematodirus helvetianus* (adult), *N. spathiger* (adult).
Lungworms (adult and fourth stage larvae): *Dictyocaulus viviparus.*
Warbles: *Hypoderma bovis* and *H. lineatum.*
Mange mites: *Psoroptes bovis, Sarcoptes scabiei* var. *bovis.*
Sucking lice: *Linognathus vituli, Haematopinus eurysternus*

The use of the product in cattle should take into account geographical differences in the occurrence patterns of parasites.

Pigs: Treatment of infections with gastro-intestinal roundworms, lungworms, mange mites and lice as shown below:
Gastro-intestinal Roundworms (adult and fourth stage larvae):
Ascaris suum, Hyostrongylus rubidus, Oesophagostomum spp, Strongyloides ransomi (adult only)
Lungworms: *Metastrongylus spp.* (adult)
Mange mites: *Sarcoptes scabiei* var. *suis*
Lice: *Haematopinus suis*

5. CONTRAINDICATIONS

Do not administer by the intravenous or intramuscular route. Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in dogs or cats as severe adverse reactions may occur (see also 'special warnings).

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 have disappeared without treatment. Mild and transient pain reactions may be seen in some pigs following subcutaneous injection. All 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 SPEICES

Cattle (beef and non-lactating dairy cattle) and Pigs

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

For single administration only by subcutaneous injection. Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle, and 33 kg of bodyweight of pigs. Replace with a fresh sterile needle after every 10 to 12 animals.

Cattle:

The product should be given only by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle. This is equivalent to 1 ml per 50 kg bodyweight. The volume administered per injection site should not exceed 10 ml.

Pigs:
In pigs, the recommended dosage level is 300 mcg ivermectin per kg bodyweight. This is equivalent to 1 ml per 33 kg bodyweight. The recommended route of administration is by subcutaneous injection into the neck.

Young pigs:
In young pigs, especially those below 16 kg for which less than 0.5 ml of the product is indicated, dosing accurately is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Massage the injection site after administration of the product. Injection of wet or dirty animals is not recommended.
To ensure administration of a correct dose, body weight 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 they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over-dosing.

10. WITHDRAWAL PERIOD

Cattle
Meat and offal: 49 days.
Do not use in lactating cows producing milk for human consumption. Do not use in cattle producing milk for human consumption or in dairy cows within 60 days prior to calving.

Pigs
Meat and offal: 28 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Do not use after the expiry date stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

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.

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 ivermectin has been reported in *Cooperia spp.* and in *Ostertagia ostertagi* in cattle. Resistance has also been reported in *Haemonchus contortus* in cattle outside 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:
In cattle, to avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or in the spine it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites. Consult your veterinarian on the correct timing of treatment.

Avermectins may not be well tolerated in non-target species. Cases of intolerance with fatal results are reported in dogs – especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises. In addition, care should be taken to avoid ingestion of spilled product or access to used containers by these other species.

Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

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

The product may cause local irritation and/or pain at the site of injection. Direct contact of the product with the skin should be avoided. Take care to avoid self administration.

Do not smoke or eat while handling the product.

Wash hands after use. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Swab septum before removing each dose. This product does not contain an antimicrobial preservative.

Pregnancy and lactation:

The product can be administered during pregnancy and lactation in cows (refer to the section on withdrawal period for details relating to the use in dairy cattle) and sows.

Fertility:

It can be used in breeding sows and boars and will not affect fertility.

Interaction with other medicinal products and other forms of interactions:

Do not combine with vaccination against lungworm. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

Overdose (symptoms, emergency procedures, antidotes):

In the case of overdose a symptomatic treatment should be given.

Cattle

Single doses of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.

Pigs

A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

Incompatibilities:

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

Other precautions

The product is very toxic to aquatic organisms and dung insects.

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

Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeat treatments on a pasture within a season should only be given on the advice of a veterinarian.

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 product should be disposed of in accordance with local requirements. The product should not enter water courses as this may be dangerous to fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The product is available in 50 ml, 250 ml and 500 ml pack sizes.

Not all pack sizes may be marketed.

Approved: 15 June 2018