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, Pigs and Sheep
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), Sheep and Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle

Meat and offal: 49 days.

Pigs

Meat and offal: 28 days.

Sheep

Meat and offal: 25 days.

Do not use in lactating cows and sheep 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.

Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.

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.

POM Prescription Only Medicine

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 Limited
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 11990/3001

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, Pigs and Sheep
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), sheepand Pigs

6. INDICATION(S)

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.

Pigs

Meat and offal: 28 days

Sheep

Meat and offal: 25 days

Do not use in lactating cows and sheep 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.
Do not use in sheep within 60 days of lambing where milk is to be used for human consumption..

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. Do not use in dogs or cats.

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.
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.
Do not eat or smoke while handling the product.
Wash hands after use.

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

Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeated treatment of animals on a pasture with an ivermectin-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

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

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 Limited
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 11990/3001

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

Package leaflet
Animec 10 mg/ml solution for injection for Cattle, Pigs and Sheep
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 Limited
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom
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

Animec 10 mg/ml solution for injection for Cattle, Pigs and Sheep

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*

Sheep: Treatment of infections with gastro-intestinal roundworms, lungworms, nasal bots and mange mites as shown below:
Gastrointestinal roundworms (adult and fourth-stage larvae):
Teladorsagia circumcincta including inhibited larvae
T. trifurcata
Haemonchus contortus including inhibited larvae
Trichostrongylus axei (adults)
T. colubriformis and T. vitrinus (adults)
Cooperia curticei
Oesophagostomum columbianum
O. venulosum (adults)
Nematodirus filicollis
Chabertia ovina
Trichuris ovis (adults)
Lungworms:
Dictyocaulus filaria (adult and fourth-stage larvae)
Protostrongylus rufescens (adults)
Nasal bots (all larval stages) :
Oestrus ovis.
Mange mites:
Psoroptes ovis

5. CONTRAINDICATIONS

Do not administer by the intravenous or intramuscular route. Do not use in cases of hypersensitivity to the active substance or to any of excipients.

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. 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. All these reactions disappeared without treatment.
Immediately following subcutaneous injection, activity suggesting pain, sometimes intense but usually transient, has been observed in some sheep.

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. Alternatively, you can report via national reporting system.

7. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle), sheep 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 sheep, and 33 kg of bodyweight of pigs. Replace with a fresh sterile needle after every 10 to 12 animals. Massage the injection site after administration of the product. Injection of wet or dirty animals is not recommended.

Cattle:

The product should be given only by subcutaneous injection at the recommended dosage level of 200 µg 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 µg 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. The volume administered per injection site should not exceed 5ml.

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.

Sheep
The recommended dose is 200 µg ivermectin per kg bodyweight (corresponding to 1 ml of the product per 50 kg bw) by subcutaneous injection over the neck.
The volume administered per injection site should not exceed 1ml.

For the treatment and control of sheep scab (*Psoroptes ovis*), two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate mites.
In young lambs weighing less than 25 kg give 0.1 ml of the product per 5 kg. The use of a syringe that can deliver as little as 0.1 ml is recommended."
This product does not contain any antimicrobial preservative. Swab septum before removing each dose.

When using the 200, 250 or 500ml pack sizes, use only automatic syringe equipment. For the 50ml pack size, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper.

9. ADVICE ON CORRECT ADMINISTRATION

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
Accuracy of the dosing device should be thoroughly checked.

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.

Sheep
Meat and offal: 25 days.

Do not use in lactating sheep producing milk for human consumption.

Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.

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:
In sheep treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although a clinical improvement may be seen, elimination of all mites may not occur.

Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite of sheep. To ensure complete control great care must be taken to avoid re–infestation, as mites may be viable for up to 15 days off the sheep. It is important that all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and untreated flocks must be avoided until at least seven days after treatment.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each herd or flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd or flock, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd or flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate

husbandry and pasture management measures. Guidance for each specific herd/flock should be sought from the responsible veterinarian.

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.

In sheep, resistance to ivermectin is widespread in *Teladorsagia circumcincta*, *Trichostrongylus* spp., *Haemonchus contortus* and in other gastro-intestinal parasite species**.**

Multiple resistance was reported in *Teladorsagia circumcincta* to benzimidazoles, macrocyclic lactones and levamisole and in *Haemonchus contortus* to ivermectin and benzimidazoles.
Multiple resistance to macrocyclic lactones has also been reported in *Psoroptes ovis* scab mites in sheep and in cattle.

The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

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:

'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.

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.

Do not eat or smoke while handling the product.

Wash hands after use.

Pregnancy and lactation:

The product can be administered during pregnancy and lactation in cows, ewes and sows. .

Fertility:

The product does not affect fertility. It can be used in breeding cows and bulls, breeding ewes and rams, in sows and boars.

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.

Sheep

At dose levels up to 4 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.

No antidote has been identified; however, symptomatic therapy may be beneficial.

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.

Long term effects on dung insects caused by continuous or repeated use cannot be excluded therefore repeated treatment of animals on a pasture with an ivermectin-containing product within a season should only be given in the absence of alternative treatments or approaches to maintain animal/flock health, as advised by a veterinarian.

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

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

The product should not enter water courses as this may be dangerous to fish and other aquatic organisms.
Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

21 September 2000

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 10 November 2023