1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec 10 mg/ml solution for injection for cattle, sheep and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol
Glycerin formal

A clear colourless, slightly viscous, sterile solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful parasites of cattle, sheep and pigs:

Cattle:
Gastro-intestinal roundworms (adult and fourth stage larvae):
Ostertagia spp (including inhibited *O. ostertagi*)
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia spp
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
N. spathiger (adult)
Toxocara vitulorum
Trichuris spp.(adult).

Lungworms (adult and fourth stage larvae):
Dictyocaulus viviparus.

Eye worms (adult):
Thelazia spp.

Warbles (parasitic stages):
Hypoderma bovis and *H. lineatum*.

Mange mites:
Psoroptes bovis,
Sarcoptes scabiei var. *bovis*.

Sucking lice:
Linognathus vituli,
Haematopinus eurysternus
Solenopotes capillatus.

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

Persistent activity
Treatment at the recommended dose rate controls re-infection with *Haemonchus placei* and *Cooperia spp.* 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.

To obtain optimal benefit from the persistent activity of the veterinary medicinal product for grazing animals it is recommended that calves which are set-stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season, provided they are set-stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture.
Treated calves should always be monitored according to good husbandry practices.

Sheep:

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

Pigs*:*

Gastrointestinal worms (adult and fourth stage larvae):

Ascaris suum,
Hyostrongylus rubidus,
Oesophagostomum spp,
Strongyloides ransomi (adult and somatic larval stage)

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var. *suis*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
This veterinary medicinal product has been formulated specifically for use in cattle, sheep and pigs. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.
Do not administer by the intravenous or intramuscular route.

3.4 Special warnings

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 veterinary medicinal 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 veterinary medicinal 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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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.

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 veterinary medicinal 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 as the veterinary medicinal 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 package leaflet or the label to the physician.
Do not eat or smoke while handling the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:

The veterinary medicinal 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 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.

Other precautions:
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.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Discomfort[1], Injection site swelling[2],

[1] Transient.
[2] Soft tissue, disappears without treatment.

Sheep:

Undetermined frequency (cannot be estimated from the available data):	Injection site pain[1]

[1] Sometimes intense but usually transient, observed immediately following subcutaneous administration

Pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site pain[1]

[1] Mild and transient following subcutaneous administration, and disappears without treatment

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The veterinary medicinal product can be administered during pregnancy and lactation in cows, ewes and sows.

Fertility:
The veterinary medicinal product does not affect fertility. It can be used in breeding cows and bulls, breeding ewes and rams, in sows and boars. The veterinary medicinal product can be given to all ages of animals.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product can be used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.

3.9 Administration routes and dosage

Subcutaneous use.
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.
The injection may be given with any standard automatic on single-dose or hypodermic syringe. Use of 17 gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended.
If using a single dose hypodermic syringe, use a separate sterile needle to withdraw the veterinary medicinal product from the container.

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.

Cattle:

The veterinary medicinal 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.

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

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.

Young lambs:
In young lambs weighing less than 25 kg give 0.1 ml of the veterinary medicinal product per 5 kg. The use of a syringe that can deliver as little as 0.1 ml is recommended.

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.

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

This veterinary medicinal 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 50 ml 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

Sheep
At dose levels up to 4 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.

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 49 days.
Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant dairy heifers within 60 days of calving.

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.

Pigs:
Meat and offal: 28 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP54AA01

4.2 Pharmacodynamics

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of this 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.

Multidrug-resistance to macrocyclic lactones is mediated by the efflux activity of ATP-binding cassette (ABC) transporters such as P-glycoproteins. Selection of resistant isolates with ivermectin leads to cross-resistance to eprinomectin and moxidectin depending upon the underlying mechanism of resistance. Molecular mechanisms of resistance involve mutations in several genetic loci associated with alterations of the glutamate-and GABA-gated chloride channels reducing the binding affinity of the molecules of macrocyclic lactones

4.3 Pharmacokinetics

<u>Maximum plasma concentration</u>

Cattle:
At a dose level of 0.2 mg ivermectin per kg a maximum plasma concentration of 35-50 ng/ml is reached in ±2 days and the half-life in plasma of 2.8 days.
It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.

Sheep
At a dose level of 0.2 mg ivermectin per kg bodyweight, a mean C_{max} of 10.976 ng/ml was reached at a median T_{max} of 40 hours, and the mean elimination half-life was 73.9 hours.

Pigs:
During trials carried out at a dose level of 0.3 mg ivermectin per kg bodyweight, peak plasma concentrations were reached in 3 (± 0.5) days and the drug persisted in plasma for up to 28 days.

Excretion: length of time and route

Cattle:
Only about 1 - 2% is excreted in the urine the remainder is excreted in the faeces, approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products.

Sheep:
The major route of excretion of ivermectin and its metabolites in sheep is faeces (99 %) with 1 % excreted in the urine.

Pigs:
Biliary excretion is also the major route of ivermectin excretion in pigs.

Environmental properties

Like other macrocyclic lactones, ivermectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of ivermectin may take place over a period of several weeks. Faeces containing ivermectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Multidose polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and aluminium overseals.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/147/001

8. DATE OF FIRST AUTHORISATION

12/01/2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).