

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
PACK LABEL**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec Super 10 mg/ml / 100 mg/ml Solution for Injection for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 10mg/ml Ivermectin and 100mg/ml Clorsulon.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50ml, 250ml or 500ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle (meat and offal): 66 days.
Milk: 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 WARNINGS

Read the package leaflet before use.

10. EXPIRY DATE

EXP: End

Shelf-life of the veterinary medicinal product after withdrawal of the first dose: 28 days.

Once broached use by ____/____.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

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.

Disposal: read package leaflet.

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

For animal treatment only.

POM-VPS

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

Chanelle Animal Health
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 11990/4054

17. MANUFACTURER'S BATCH NUMBER

BN:

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PRINTED CARTON**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec Super10 mg/ml / 100 mg/ml Solution for Injection for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 10mg/ml Ivermectin and 100mg/ml Clorsulon.

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

50ml, 250ml or 500ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

Subcutaneous injection

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 66 days.

Milk: 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 WARNINGS

The product is not to be used intramuscularly or intravenously.

10. EXPIRY DATE

EXP: End

Shelf-life of the veterinary medicinal product after withdrawal of the first dose: 28 days.

Once broached use by ____/____.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

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16. MARKETING AUTHORISATION NUMBER

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17. MANUFACTURER'S BATCH NUMBER

BN:

PACKAGE LEAFLET

Animec Super 10 mg/ml / 100 mg/ml Solution for Injection for Cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom

NAME AND ADDRESS THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Chanelle Pharmaceutical Manufacturing Ltd.
Loughrea, Co. Galway
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec Super 10 mg/ml / 100 mg/ml Solution for Injection for Cattle

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

Contains 10mg/ml Ivermectin and 100mg/ml Clorsulon.

4. INDICATION(S)

For the treatment of mixed infestations of adult liver fluke and gastro-intestinal roundworms, lungworms, eye worms, and/or mites and lice of beef and non lactating dairy cattle.

Animec Super Solution for Injection for Cattle is a broad-spectrum endo- and ecto-parasiticide. One dose is effective against many parasites. It is convenient to use.

Animec Super Solution for Injection for Cattle treats:

PARASITE	Adult	L4	Inhibited L4
Gastrointestinal roundworms			
<i>Ostertagia ostertagi</i>	+	+	+
<i>Ostertagia lyrata</i>	+	+	
<i>Haemonchus placei</i>	+	+	
<i>Trichostrongylus axei</i>	+	+	
<i>Trichostrongylus colubriformis</i>	+	+	
<i>Cooperia oncophora</i>	+	+	
<i>Cooperia punctata</i>	+	+	
<i>Cooperia pectinata</i>	+	+	
<i>Bunostomum phlebotomum</i>	+	+	
<i>Oesophagostomum radiatum</i>	+	+	
<i>Strongyloides papillosus</i>	+		
<i>Nematodirus helvetianus</i>	+		
<i>Nematodirus spathiger</i>	+		
<i>Trichuris</i> spp	+		

PARASITE	Adult	L4	Inhibited L4
Lungworms			
<i>Dictyocaulus viviparus</i>	+	+	
Eye worms			
<i>Thelazia</i> spp.	+		

PARASITE	Adult	Immature
Liver fluke		
<i>Fasciola hepatica</i>	+	
Warbles (parasitic stages)		
<i>Hypoderma bovis</i>		+
<i>H. lineatum</i>		+
Mange mites		
<i>Psoroptes bovis</i>	+	+
<i>Sarcoptes scabiei var bovis</i>	+	+
Sucking lice		
<i>Linognathus vituli</i>	+	+
<i>Haematopinus eurysternus</i>	+	+
<i>Solenopotes capillatus</i>	+	+

PROLONGED ACTIVITY

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, Animec Super Solution for Injection for Cattle given at the recommended dosage of 1ml per 50kg bodyweight controls re-infection with the following nematodes up to the duration shown:

PARASITE	NO. OF DAYS AFTER TREATMENT
Barbers pole worm – <i>Haemonchus placei</i>	14
Small intestinal worm – <i>Cooperia spp</i>	14
Hairworm – <i>Trichostrongylus axei</i>	14
Brown stomach worm – <i>Ostertagia ostertagi</i>	21
Nodular worm – <i>Oesophagostomum radiatum</i>	21
Lungworm – <i>Dictyocaulus viviparus</i>	28

Ivermectin Clorsulon 10/100mg/ml may also be used as an aid in the treatment of biting lice (*Damalinea bovis*) and the mange mite (*Chorioptes bovis*), but complete elimination may not occur.

5. CONTRAINDICATIONS

Do not use this product intravenously or intramuscularly.
Ivermectin Clorsulon 10/100mg/ml is a low volume product authorised for use in cattle. It must not be used in other species as severe adverse reactions, including fatalities in dogs, may occur, especially Collies, Old English Sheepdogs and related breeds and crosses. Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

6. ADVERSE REACTIONS

Transient 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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

DOSAGE AND ADMINISTRATION

For subcutaneous use.

Dosage: 1ml of the product per 50 kg bodyweight (based on a recommended dosage level of 200µg of ivermectin and 2mg of clorsulon per kg bodyweight). For example:

Bodyweight (kg)	Dose volume (ml)	Doses per 50ml pack	Doses per 250ml pack	Doses per 500ml pack
Up to 50	1	50	250	500
51-100	2	25	125	250
101-150	3	16	83	166
151-200	4	12	62	125
201-250	5	10	50	100
251-300	6	8	40	83

Over 300kg give 1ml per 50kg bodyweight.

To ensure a correct dosage, body weight should be determined as accurately as possible. 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. Inject only by the subcutaneous route.

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.

Divide doses in excess of 10ml between different injection sites.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

A sterile 17 gauge (15-20 mm) needle is recommended.

Different injection sites should be used for other parenteral products administered concurrently. When using the 500 ml pack size use only automatic syringe equipment. For the 50 ml pack size, use of a multidose syringe is recommended.

The product should be administered under the loose skin in front of or behind the shoulder.

For animal treatment only.

10. WITHDRAWAL PERIODS

Meat and offal: 66 days

Milk: 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.

Keep the container in the outer carton in order to protect from light.

Shelf-life of the veterinary medicinal product after withdrawal of the first dose: 28 days.

Discard unused material.

12. 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:

Special precautions for use in animals:

- 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 *Ostertagia ostertagi* and *Cooperia* spp. in cattle within the EU. Therefore, the use of this product 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.

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

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the product at the end of the period of fly activity and before the larvae reach their resting sites: seek professional advice on the correct timing of treatment.

Divide doses in excess of 10 ml between different injection sites and use different sites to those used for other parenteral medications.

User Warnings

Do not smoke or eat whilst handling the product.

Wash hands after use.

Wear gloves and glasses when handling the veterinary medicinal product.

Take care to avoid self-injection: the product may cause local irritation and/or pain at the injection site.

In case of accidental self-injection, seek medical advice and show the label to the doctor. Direct contact with the skin should be avoided.

Environmental warnings

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 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

Pregnancy and Lactation:

Can be used in pregnancy and lactation.

Fertility:

Can be used in breeding animals.

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.

Interaction with other medicinal products and other forms of interaction:

None known.

Incompatibilities:

In the absence of compatibilities 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

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

MODE OF ACTION

Ivermectin acts on the nervous system of nematode and arthropod parasites. It first paralyses, then kills them. At therapeutic usage rates it has no effect on the nervous system of cattle.

Clorsulon acts on enzymes involved in energy generation in liver fluke. At therapeutic usage rates it has no effect on the equivalent systems of cattle.

At the recommended usage rate Animec Super Solution for Injection for Cattle has no adverse effects on breeding performance of cattle. At therapeutic usage rates it has no effect on the nervous system of cattle.

Package quantities: 50ml, 250ml and 500ml containers

Not all pack sizes may be marketed.

Legal Category: POM-VPS To be supplied only on veterinary prescription.

Marketing Authorisation Number:

Pharmacotherapeutic group: Endectocide, anthelmintic, flukicide

Approved 13 March 2020

A handwritten signature in black ink, appearing to read "Hunter.", is written below the approval date.