

PACKAGE INSERT: ECOMECTIN

FOR ANIMAL USE ONLY

ECOMECTIN 1 % Injectable Solution ①†

RSA G2275 Act 36/1947

Namibia S0 V02/18.1.2/1145

Zambia: 414/701V

CAUTION

STORAGE INSTRUCTIONS

Store below 30 °C away from sunlight.

COMPOSITION

Ivermectin 1 % m/v

INDICATIONS

Antiparasitic remedy for cattle and sheep, kills mange mites on pigs.

WARNINGS

- Do not slaughter cattle or sheep for human consumption within 21 days of last treatment, and pigs within 28 days of last treatment
- Do not use in lactating cattle where milk or milk products are used for human consumption.
- Do not use intramuscularly or intravenously.
- Keep out of reach of children, uninformed persons and animals.
- Do not use in dairy cattle within 28 days of calving.
- Although this remedy has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

- Do not eat, drink or smoke while handling the product.
- Store bottle in carton to protect from light.
- Wash hands thoroughly after use.
- Cattle should be vaccinated against Clostridial infections (e.g. Black quarter).
- Sheep should be vaccinated against pulpy kidney (entero-toxaemia) before treatment.
- Temporary discomfort has been observed in animals following subcutaneous injection. The pain reaction is sometimes intense, but usually transient. A low incidence of soft tissue swelling at the injection site has been observed. These reactions have disappeared without treatment.

INDICATIONS:

EFFICACY FOR CATTLE

Internal parasites of cattle: for the treatment of gastro-intestinal roundworms, *Parafilaria bovicola* (false bruising) and eye worm (*Thelazia*).

ECOMECTIN 1 % Injectable Solution is effective against the following internal parasites of cattle when given subcutaneously at the recommended dose of 200 µg/kg body mass.

Cattle Roundworms	Immature	Adult	* Controls against re-infestation for
Wireworm	*	*	14 days
Brown stomachworm	*	*	21 days
Cattle Bankruptworm	*	*	14 days
Hookworm	*	*	
Nodular worm	*	*	
<i>Thelazia</i> (Eyeworm)	*		
<i>Parafilaria bovicola</i> (false bruising)	** (An interval of 70 days must elapse after treatment to allow lesions to heal)		

* Control = ≥ 90 % effective

** Aid in Control = 60 – 89 % effective

The list contains the more important endoparasite species. This anthelminthic may also be effective against other species. For more information consult your veterinarian.

External parasites of cattle:

- Kills sucking and biting lice and mange mites.
- Controls sand tampan infesting cattle for up to 3 days after treatment.
- Kills cattle screw-worms present at time of injection. Protects against screw-worms strikes for 2 weeks after administration.
- Controls blue ticks (*Boophilus* spp) on cattle. For control of blue ticks, treatment must be repeated every 21 days.

EFFICACY FOR SHEEP

External parasites.

- Kills sheep scab mites.
- Controls Australian itch mites.
- * Nasal worm all stages (1st, 2nd and 3rd instar larvae)
* (Control = ≥ 90 % effective)

Roundworm species	Immature	Adult
Wireworm	*	*
Brown stomachworm	*	*
Bankruptworm	*	*
Long-necked bankruptworm	**	-
Hookworm	*	*
Nodular worm	*	*
Large-mouthed bowelworm	*	*
Lungworm	*	*

* Control = ≥ 90 % effective

** Aid in Control = 60 – 89 % effective

The list contains the more important endoparasite species. This anthelmintic may also be effective against other species. For more information consult your veterinarian.

EFFICACY FOR PIGS

External parasites of pigs.

Kills mange mites (*Sarcoptes scabiei* var *suis*). (Recommended dose 300 µg/kg).

NOTE: ECOMECTIN 1 % Injectable Solution has a persistent drug level sufficient to control mite infestations throughout the duration of the life cycle. However, since the effect is not immediate, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities. Generally, pigs should not be moved to clean quarters or exposed to uninfested pigs for approximately one week after treatment. Sows should be treated at least one week before farrowing to minimise transfer of mites to newborn baby pigs.

DIRECTIONS FOR USE – USE ONLY AS DIRECTED

DOSAGE:

CATTLE: ECOMECTIN 1 % Injectable Solution for cattle should be given only by subcutaneous injection at the approved dosage level of 200 µg ivermectin per kilogram of body mass. Each ml contains 10 mg of ivermectin, sufficient to treat 50 kg of body mass.

Body mass (kg)	Dose volume (ml)	Body mass (kg)	Dose volume (ml)
Up to 50	1	301 - 350	7
51 - 100	2	351 - 400	8
101 - 150	3	401 - 450	9
151 - 200	4	451 - 500	10
201 - 250	5	501 - 550	11
251 - 300	6	551 - 600	12

Administration: ECOMECTIN 1 % Injectable Solution is to be given by subcutaneous injection only. Do not administer intramuscularly or intravenously. In cattle inject under the loose skin in front of or behind the shoulder. Use of a 16-gauge 2,0 cm needle is suggested. Use sterile equipment and follow aseptic procedures.

Appropriate vaccination precautions should be taken in areas where the risk of Clostridial infections of cattle such as black quarter (sponssiekte) and malignant oedema are present.

Compatibility : ECOMECTIN 1 % Injectable Solution may be used in cattle concurrently with clostridial vaccines, given at separate injection sites.

DOSAGE: SHEEP : ECOMECTIN 1 % Injectable Solution should only be given at the following recommended dosage levels:

Body mass (kg)	Dose volume (ml)
0 – 25	0,5
26 - 50	1,0
51 - 75	1,5
76 - 100	2,0

Administration: ECOMECTIN 1 % Injectable Solution is to be given by subcutaneous injection only. Do not administer intramuscularly or intravenously. The solution may be administered with any standard automatic or single-dose equipment. Use aseptic technique. The loose skin behind the shoulder, the skin under the foreleg (axilla) and the inside of the thigh are suitable sites for administration. Ensure that the needle is carefully inserted and that the solution does not leak from the injection site. In woolly sheep, ensure that the needle has penetrated the wool and skin before delivering the dose.

For treatment of sheep scab outbreaks a single dose of 1 ml/50kg (200 µg/kg) can be given. This should be done under Government supervision.

NOTE: *When treating an outbreak of sheep scab it is essential that:*

- a) *All sheep on the farm must be accurately treated with the correct dose and marked after treatment.*
- b) *All animals must be checked 7 - 10 days after treatment and any animals not marked must be treated.*
- c) *Care must be taken that the full dose is administered to each sheep.*
- d) *Under certain circumstances two treatments 7 days apart may be required to eliminate all scab mites.*

An autumn treatment will kill third stages of nasal worm and a spring treatment will offset new infestations of this parasite.

A treatment in late autumn will remove residual summer roundworm burdens as well as first infestations of those roundworm species stimulated by cooler weather conditions. The spring "off-shears" treatment will remove roundworm burdens which have built up during the winter and early spring infestations stimulated by the first rains. This will contribute to reducing the contamination of "clean" summer grazing.

DOSAGE: PIGS: The approved dose level is 1,0 ml per 33 kg (300 µg/kg) subcutaneously. Administer to pigs subcutaneously in the neck.

Body mass (kg)	Dose volume (ml)
Up to 50	1,5
51 - 100	3,0
101 - 150	4,5
151 - 200	6,0
201 - 250	7,5
251 - 300	9,0
301 - 350	10,5
351 - 400	12,0

Instructions for use with automatic dosing equipment (200 ml and 500 ml packs):

- Disinfect all needles and syringes before using by boiling in clean water for 15 to 20 minutes.
- Boiled needles should be stored in an antiseptic solution before use and changed frequently when injecting animals.
- Remove the draw-off assembly from the sterile pack. Handle carefully to avoid contamination.
- Connect the plastic tube firmly to dosing syringe. Use stepped adaptor provided if needed.
- Remove cap from bottle and disinfect rubber stopper with methylated spirits or other suitable chemical disinfectant. Hold bottle upright and fully insert draw-off needle into centre of rubber stopper.
- Hang bottle comfortably in inverted position from neck, shoulder, or belt. Use attachment tapes provided.
- Gently prime injector. Equipment is now ready for use.
- After use, remove draw-off assembly from pack and flush out entire apparatus with water before storing.

- If connecting tube is re-used, it should be boiled for 15 to 20 minutes before use along with the injecting syringe and needles.
- Store partly used bottle in carton to protect from light.
- Do not re-use empty bottles.

ENVIRONMENTAL SAFETY:

Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time.

Drug containers and any residual contents should be disposed of safely (e.g. by burying or incinerating), as free ivermectin may adversely affect fish and certain water-borne organisms.

PACKAGING SIZE:

20ml, 50 ml, 200 ml, 500 ml, 1 L

REGISTRATION HOLDER:

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† Macrocyclic lactone

VOUBILJET: ECOMECTIN

SLEGS VIR DIEREGERBRUIK

ECOMECTIN 1 % Inspuitbare Oplossing ①†

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Namibia S0 V02/18.1.2/1145

Zambia: 414/701V

VERSIGTIG

BERGINGSAAWYSINGS

Bewaar onder 30° C weg van sonlig.

SAMESTELLING

Ivermektien 1 % m/v

AANDUIDINGS

Antiparasitiese middel vir beeste en skape, dood skurfte myte op varke.

WAARSKUWINGS

- Moenie beeste of skape vir menslike gebruik slag binne 21 dae vanaf laaste behandeling en varke binne 28 dae vanaf laaste behandeling nie.
- Moenie in melkbeeste waarvan die melk vir menslike gebruik aangewend word, gebruik nie.
- Moenie in melkbeeste binne 28 dae van kalwing gebruik nie.
- Moenie binnespiers of binnears gebruik nie.
- Hou buite bereik van kinders, oningeligte persone en diere.
- Alhoewel hierdie produk breedvoerig onder 'n wye verskeidenheid van toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwittig die registrasiehouer.

VOORSORGMAATREËLS

- Moenie eet, drink of rook terwyl die produk hanteer word nie.
- Berg bottel in kartonhouer om te beskerm teen sonlig.
- Was hande deeglik na gebruik.
- Beeste behoort ingeënt te word teen klostridiale infeksies (bv. Sponssiekte).
- Skape behoort ingeënt te word teen bloednier (enterotoksemie) voor behandeling.
- Tydelike ongemak was waargeneem by diere na onderhuidse inspuitings. Die pynreaksie is soms intens, maar is gewoonlik kortstondig. 'n Paar gevalle van sagteweefsel swelling by die inspuitplek is ook waargeneem. Hierdie reaksies verdwyn sonder behandeling.

INDIKASIES:

EFFEKTIWITEIT IN BEESTE

Inwendige parasiete by beeste: vir die behandeling van gastro-intestinale rondewurms, *Parafilaria bovicola* (valskneusing) en oogwurm (*Thelazia*).

ECOMECTIN 1 % Insputbare Oplossing is effektief teen die volgende inwendige parasiete in beeste wanneer onderhuids toegedien word teen die aanbevole dosis van 200 µg/kg liggaamsmassa.

Beeste Rondewurms	Onvolwasse	Volwasse	* Beheer teen hersmetting vir
Haarwurm	*	*	14 dae
Bruinmaagwurm	*	*	21 dae
Beesbankrotwurm	*	*	14 dae
Haakwurm	*	*	
Knoppieswurm	*	*	
<i>Thelazia</i> (Oogwurm)	*		
<i>Parafilaria bovicola</i> (Valkneusing)	** ('n Tussenpose van 70 dae moet verloop na behandeling, om toe te laat dat letsels gesond word).		

* Beheer = ≥ 90 % effektief

** Hulp in die beheer = 60 – 89 % effektief

Hierdie lys bevat die meer belangrike endoparasitiese spesies. Dit kan ook effektief teen ander spesies gebruik word. Vir verdere inligting raadpleeg u veearts.

Uitwendige parasiete in beeste.

- Dood suigende en bytende luise en skurftemyte.
- Beheer sandtampansbesmetting by beeste vir tot 3 dae na behandeling.
- Dood spykerwurm wat teenwoordig is wanneer ingespuet word. Beskerm teen spykerwurmbesmettings vir twee weke na toediening.
- Beheer blou bosluise (*Boophilus* spp) op beeste + vir beheer van blou bosluis moet behandeling elke 21 dae herhaal word.

EFFEKTIWITEIT IN SKAPE

Uitwendige parasiete.

- Dood skaap brandsiekte myte.
- Beheer Australiese jeukmyte.
- * Neuswurm alle stadia (1ste, 2de en 3de instar larwes).
- * Beheer = ≥ 90 % effektief

Rondewurm spesies	Onvolwasse	Volwasse
Haarwurm	*	*
Bruinmaagwurm	*	*
Bankrotwurm	*	*
Langnekbankrotwurm	**	-
Haakwurm	*	*
Knoppieswurm	*	*
Grootbekwurm	*	*
Longwurm	*	*

* Beheer = ≥ 90 % effektief

** Hulp in die beheer = 60 – 89 % effektief

Hierdie lys bevat die meer belangrike endoparasitiese spesies. Dit kan ook effektief teen ander spesies gebruik word. Vir verdere inligting raadpleeg u veearts.

EFFEKTIWITEIT IN VARKE

Uitwendige parasiete by varke: Dood skurftemyte (*Sarcoptes scabiei* var *suis*). (Aanbevole dosis 300 µg/kg).

NOTA:: ECOMECTIN 1 % Inspuitbare Oplossing het 'n blywende verdowende vlak wat genoegsaam is om myt infestasies te beheer regdeur die duur van die lewenssiklus. Maar, aangesien die effek nie onmiddellik in werking tree nie, moet blootstelling aan herinfestering deur onbehandelde diere of besmette fasiliteite verhoed word. Normaalweg moet varke nie na skoon kwartiere verskuif word nie of blootgestel word aan onbesmette varke vir ongeveer een week na behandeling nie. Sôe behoort ten minste een week voor die geboorte van 'n werpsel behandel te word om die oordrag van myte op baba varkies te voorkom.

GEBRUIKSAANWYSINGS – GEBRUIK SLEGS SOOS AANGEDUI

DOSIS:

BEESTE : ECOMECTIN 1 % Inspuitbare Oplossing moet slegs onderhuids teen die aanbevole dosisvlak van 200 µg ivermektien per kilogram liggaamsmassa toegedien word. Elke ml bevat 10 mg ivermektien wat genoegsaam is om 50 kg liggaamsmassa te behandel.

Liggaamsmassa (kg)	Dosis volume (ml)	Liggaamsmassa (kg)	Dosis volume (ml)
Tot 50	1	301 - 350	7
51 - 100	2	351 - 400	8
101 - 150	3	401 - 450	9
151 - 200	4	451 - 500	10
201 - 250	5	501 - 550	11
251 - 300	6	551 - 600	12

Toediening: ECOMECTIN 1 % Inspuitbare Oplossing moet slegs d.m.v. onderhuidse inspuiting toegedien word. Moet nie binnespiers of binnears toedien nie. By beeste spuit onder die los vel voor of agter die skouer. Die gebruik van 'n 16-maat 2,0 cm naald word aanbeveel. Gebruik gesteriliseerde gereedskap en volg aseptiese prosedures.

Goedgekeurde inentingsvoorsorgmaatreëls moet geneem word in areas waar die risiko van Klostridiale infeksies by beeste soos sponssiekte en kwaadaardige oedema teenwoordig is.

Kruisbaarheid : ECOMECTIN 1 % Inspuitbare Oplossing mag gelyktydig met klostridiale inentings in beeste gebruik word maar moet toegedien word op aparte inspuitplekke.

DOSIS: SKAPE : ECOMECTIN 1 % Inspuitbare Oplossing moet slegs toegedien word teen die volgende aanbevole dosisvlakke:

Liggaamsmassa (kg)	Dosis volume (ml)
0 – 25	0,5
26 - 50	1,0
51 - 75	1,5
76 - 100	2,0

Toediening: ECOMECTIN 1 % Inspuitbare Oplossing moet slegs d.m.v. onderhuidse inspuiting toegedien word. Moet nie binnespiers of binnears toegedien word nie. Die oplossing kan d.m.v. enige standaard outomatiese of enkeldosis apparaat toegedien word. Gebruik steriele tegnieke. Die los vel agter die skouer, die vel onder die voorbeen (oksel) en die binnekant van die dy is geskikte plekke vir toediening. Verseker dat die naald versigtig ingesteek word en dat die oplossing nie vanuit die inspuitplek lek nie. In wollerige skape, verseker dat die naald deur die wol en die vel penetreer alvorens die dosis toegedien word.

Vir die behandeling van die uitbraak van brandsiekte by skape word 'n enkele dosis van 1 ml/50 kg (200µg/kg) toegedien. Dit moet onder toesig van die Staat gedoen word.

LET WEL: Wanneer 'n uitbraak van brandsiekte by skape behandel word, is dit noodsaaklik dat:

- a) Al die skape op die plaas akkuraat met die korrekte dosis behandel word en na behandeling gemerk word.
- b) Al die diere moet 7 - 10 dae na behandeling ondersoek word en enige skape wat nie gemerk is nie moet behandel word.
- c) Sorg moet gedra word dat die volle dosis aan elke skaap toegedien word.
- d) Onder sekere omstandighede mag twee behandelings, 7 dae uitmekaar, nodig wees om alle brandsiekmyte te elimineer.

'n Herfsbehandeling sal derde stadia neuswurm dood en 'n lentebehandeling sal nuwe infestاسies van hierdie parasiet teëwerk.

'n Behandeling in die laat-herfs sal oorblyfsels van rondewurms verwyder asook die eerste infestاسies van die rondewurm spesies wat gestimuleer word deur koeler weersomstandighede. Die lente "na-skeer" behandeling sal rondewurm besmettings wat opgebou het gedurende die winter en vroeë lente besmettings wat gestimuleer word deur die eerste reën verwyder. Dit sal bydra tot die vermindering van die besmetting van "skoon" somer weiding.

DOSIS: VARKE: Die aanbevole dosisvlak is 1,0 ml per 33 kg (300 µg/kg). Word onderhuids in die vark se nek toegedien.

Liggaamsmassa (kg)	Dosis volume (ml)
Tot 50	1,5
51 - 100	3,0
101 - 150	4,5
151 - 200	6,0
201 - 250	7,5
251 - 300	9,0
301 - 350	10,5
351 - 400	12,0

Instruksies vir die gebruik van outomatiese doseringsapparaat (200 ml en 500 ml verpakings):

- Ontsmet alle naalde en spuite alvorens gebruik word deur dit in skoon water vir 15 tot 20 minute te kook.
- Gekookte naalde moet voor gebruik in 'n steriele oplossing geberg word en gereeld geruil word wanneer diere ingespuut word.
- Verwyder die aftrek montering van die steriele houer. Hanteer versigtig om kontaminاسie te vermy.
- Verbind die plastiek buis stewig met die doseringspuit. Gebruik afgemete konneksie

wat verskaf word indien nodig.

- Verwyder dop van bottel en ontsmet rubberprop met brandspiritus of enige ander gepaste chemiese ontsmettingsmiddel. Hou bottel regop en steek die aftapnaald deur die middel van die rubberprop.
- Hang bottel in 'n gemaklike omgekeerde posisie om die nek, skouer of middel. Gebruik bande wat verskaf word.
- Vul spuit versigtig. Apparaat is nou gereed vir gebruik.
- Na gebruik, verwyder aftrek montering van die houer en spoel die hele apparaat uit met water voordat dit gebêre word.
- Indien hegtingsbuis her-gebruik word, moet dit vir 15 to 20 minute gekook word alvorens dit weer gebruik word met die spuit en naalde.
- Berg halfgebruikte bottel in kartonhouer om dit teen sonlig te beskerm.
- Moet nie leë bottels weer gebruik nie.

OMGEWINGSVEILIGHEID:

Studies het getoon dat wanneer ivermektien in aanraking kom met die grond, bind dit onmiddellik en stewig met die grond en raak na 'n ruk onaktief.

Medisyne houers en enige residuele inhoud moet veilig weggegooi word (bv. deur dit te begrawe of verbrand), aangesien vry ivermektien negatiewe effekte op visse en sekere water organismes kan hê.

AANBIEDING:

Houers van 20 ml, 50 ml, 200 ml, 500 ml, 1 L

REGISTRASIEHOUER:

ECO Dieregesondheid Suider Afrika (Edms) Bpk

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† Makrosikliese laktoon