

CARTON AND VIAL LABELS

FOR ANIMAL USE ONLY

IMIDOX® INJECTION

Reg. No. G3257 Act 36/1947

Treatment and prevention of Babesiosis in Cattle.
Treatment of Anaplasmosis in Cattle.

CAUTION

Store between 2 and 8 °C. Do not freeze. Protect from light.
Use the contents of the vial within 28 days of initial broaching and discard any unused portion.

Contains: Imidocarb dipropionate 12 % m/v

20 ml or 100 ml

* Imidocarb dipropionate

REGISTRATION HOLDER:

Afrivet Business Management (Pty) Limited

Co. Reg. No. 2000/0112963/07

P O Box 2009, FAERIE GLEN, 0043 R.S.A.

Tel: 012 991 6416

Helpline: 0860 VEEARTS

Website: www.afrivet.co.za

SIDE PANEL

WARNINGS

Do not slaughter for human consumption within 28 days of last treatment.

Do not use in lactating cows where milk or milk products may be used for human consumption.

Keep out of reach of children, uninformed persons and animals.

Do not exceed recommended dosage.

Treatment of overdosage is symptomatic and supportive.

If poisoning occurs, contact a doctor or healthcare professional.

Although this product has been tested extensively 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

Avoid intravenous administration.

The injection site should be swabbed clean with antiseptic prior to dosing.

Dispose of empty containers by wrapping with paper and putting in garbage.

Discarded needles should immediately be placed in a designated and appropriately labelled sharps container.

DOSAGE AND DIRECTIONS FOR USE

For full particulars refer to enclosed package insert.

Exp.:

Mnf:

Lot:

MAIN PANEL

SLEGS VIR DIEREGBRUIK

IMIDOX® INJECTION

Reg. Nr. G3257 Wet 36/1947

Behandeling en voorkoming van Babesiose in Beeste.
Behandeling van Anaplasiose in Beeste.

VERSIGTIG

Stoor tussen 2 en 8 °C. Moet nie vries nie. Beskerm teen lig.
Gebruik inhoud van die fles binne 28 dae na die eerste gebruik, vernietig alle ongebruikte produk.

Samestelling: Imidokarbdipropionaat 12 % m/v

20 ml of 100 ml

* Imidokarbdipropionaat

REGISTRASIEHOUER

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Mpy. Reg. No. 2000/0112963/07

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SIDE PANEL

WAARSKUWINGS

Moet nie diere slag vir menslike gebruik binne 28 dae na behandeling.

Moet nie in lakterende koeie waar die melk of melk produkte vir menslike gebruik bestem is gebruik nie.

Hou buite bereik van kinders en oningeligte persone en diere.

Moet nie voorgeskrewe dosis oorskry nie.

Behandeling van oordosering is simptome en ondersteunend.

Indien vergifting plaasvind raadpleeg 'n geneeshere of professionele gesondheidswerker.

Alhoewel hierdie produk onder 'n wye verskeidenheid van toestande getoets is, mag die faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwitting die registrasiehouer.

VOORSORGMATREËLS

Verhoed binnearse toediening.

Die inspuitlek moet ontsmet word voor inspuiting.

Raak ontslae van leë houers deur dit in papier toe te draai en in vullis houer te plaas.

Weggooibare naalde moet onmiddelik in 'n vooraf bestemde houer wat duidelik gemerk is geplaas word.

DOSIS EN GEBRUIKSAANWYSINGS

Vir volle besonderhede, verwys na ingeslote voubiljet.

Verval :

Vervaardig :

Lot :

For Animal Use Only

IMIDOX Injection

Reg. No. G3257 Act 36/1947

DOSAGE FORM

Injectable solution.

COMPOSITION

Each 1 mL contains 120 mg imidocarb dipropionate equivalent to imidocarb 85 mg per mL.

INDICATIONS

Imidox cures redwater (Babesiosis) and tick-borne gallsickness (Anaplasmosis) in cattle. It can be used in cattle for the prevention of Asiatic redwater for up to 4 weeks and African redwater for up to 8 weeks. Imidox is also indicated for the treatment of equine and canine Babesiosis.

STORAGE INSTRUCTIONS

Store between 2 and 8 °C. Do not freeze. Protect from light.

Use the contents of the vial within 28 days of initial broaching and discard any unused portion.

WARNINGS

Do not slaughter for human consumption within 28 days of last treatment.

Do not use in lactating cows where milk or milk products may be used for human consumption.

Keep out of reach of children, uninformed persons and animals.

Do not exceed recommended dosage.

Do not use the product after expiry date as it may be ineffective or harmful to the animal.

A swelling may occur at the injection site in some animals which would disappear without forming abscesses.

Salivation may be seen after treatment.

Protect from light.

Treatment of overdosage is symptomatic and supportive.

If poisoning occurs, contact a doctor or healthcare professional.

Although this product has been tested extensively 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

Avoid intravenous administration.

The injection site should be swabbed clean with antiseptic prior to dosing.

Dispose of empty containers by wrapping with paper and putting in garbage.

Discarded needles should immediately be placed in a designated and appropriately labelled sharps container.

DOSAGE

CATTLE

Therapy of babesiosis: 1 mL per 100 kg bodyweight by subcutaneous or intramuscular injection.

Very severe cases may require a second dose 24 hours following the first injection.

Chemoprophylaxis of bovine babesiosis: 2.5 mL per 100 kg bodymass. The prophylactic period for *Babesia bovis* is up to 4 weeks and for *Babesia bigamina* up to 8 weeks. In the field it is possible under certain circumstances e.g. high challenge, that outbreaks of *B. bovis* could occur as early as 18 days after prophylactic administration of Imidox. Immunity develops if treated animals are subjected to challenge during the prophylactic period. Do not repeat the dose within 4 weeks.

Therapy of Anaplasmosis: 2.5 mL per 100 kg bodymass by subcutaneous or intramuscular injection.

IMIDOX (G3257)

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Transfer of registration from Pfizer Laboratories (Pty) Ltd to Afrivet Business Management (Pty) Limited

Submitted: 27/02/2009 (1st draft)

HORSES

Equine babesiosis: *B. caballi*: 2 ml per 100 kg bodymass by intramuscular injection. *B. equi*: 2 ml per 100 kg bodymass by intramuscular injection. Two treatments at 24 hours may be required.

DOGS

Canine babesiosis: 0.5 ml per 10 kg bodymass by subcutaneous injection.

DIRECTIONS FOR USE

Sterilise all injection apparatus by boiling (or equivalent) before use. Avoid use of strong disinfectants on apparatus.

Maintain cleanliness at all times.

Keep needles sharp and clean. Replace frequently.

Use shortest needle possible, certainly not exceeding 15 mm.

As far as possible avoid injection of animals during wet weather or under dusty conditions.

This product should be injected only under the skin, preferably high on the neck behind the ear.

PHARMACOLOGICAL ACTION

Imidocarb dipropionate is a derivative of the carbanilide antiprotozoals. Although the exact mode of action of the drug is not known a possible mechanism is interference with cellular repair and replication through binding with DNA. Imidocarb is highly effective against infections caused by *Babesia* and *Anaplasma spp.*

Babesiosis, also known as tick fever or redwater is caused by tick-borne protozoan parasites of the genus *Babesia*. Babesiosis is characterised by fever, anaemia, icterus and haemoglobinuria. It is a widespread disease most common in tropical regions where the cattle tick *Boophilus decoloratus* and *Boophilus microplus* is abundant. The most significant parasites causing babesiosis in cattle are *Babesia bovis* and *Babesia bigemina*.

In endemic areas infection with *Babesia* is acquired by calves at a young age but infection does not manifest as clinical disease due to natural resistance. Animals infected early act as carriers of infection, remaining immune to clinical disease as long as infection persists. Reinfection constantly occurs in endemic areas. Without reinfection, immunity is lost within several months and clinical disease result.

Clinical disease most commonly occurs when:

- i. susceptible cattle are transported from a non-endemic to an endemic region
- ii. contact occurs between infected and non-infected cattle
- iii. epidemics occur following introduction of infection to non-endemic areas or sudden increases in tick populations where environmental conditions are favourable
- iv. the tick vector population drops due to altered weather patterns or tick control measures reducing reinfection rate and therefore immunity

Treatment of clinical cases of babesiosis with **Imidox** is most effective when cattle are treated early in the course of the disease and in combination with supportive therapy such as provision of shade.

Where disease is severe, repeat treatment with **Imidox** may be required after 24 hours.

Sterilisation of infection with **Imidox** results in complete elimination of Babesial parasites from carrier animals. Elimination of carriers is necessary where movement of cattle from an endemic to a non-endemic area would otherwise result in infection of susceptible cattle.

Prevention of *Babesia* infection may be achieved by treatment of susceptible animals with **Imidox** prior to introduction into an endemic area. Over time the level of imidocarb in the animal's body diminishes, allowing a small number of parasites to establish infection while the animal is still protected by the drug. The result is the development of immunity to disease without the occurrence of clinical signs. However if there is no exposure

to infection during the period of weaning imidocarb levels, the animal will become susceptible to clinical disease. One dose of **Imidox** will provide protection from infection for up to 4 weeks. **Imidox** is useful for the protection against babesiosis where a short passage through an endemic area is planned for a herd of susceptible cattle. Outbreaks of babesiosis may be controlled by administration of preventative doses of **Imidox** to all animals exposed to infection, however vaccination will still be necessary at a later time.

Anaplasmosis is a tick-borne disease caused by the rickettsial organism *Anaplasma marginale* which parasitises red blood cells. The course of the disease may be prolonged over months. The severity of disease resulting from infection tends to increase with age, reaching up to 50 % mortality in susceptible adult cattle.

The clinical signs of anaplasmosis relate to the acute anaemia that results and include fever, jaundice and emaciation. Decreased milk production and abortion are common. The clinical signs of anaplasmosis and babesiosis are very similar however the dose rate for their treatment differ. It is therefore important to prepare blood smears from suspect cases for laboratory examination in order to distinguish between them.

Imidox is an effective treatment for anaplasmosis at the recommended dose rate. Supportive therapy should be instituted including provision of shade and plenty of feed and water. In severe cases blood transfusion may be required. Recovered animals should be monitored for approximately 4 weeks following treatment, as re-treatment may be necessary if relapse occurs. To reduce risk of transmission of the disease the herd should be dipped several times for tick control.

PRESENTATION

Imidox Injection is available in 20 ml amber glass or 100 ml amber polyethylene multidose vials in cartons.

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Imidox is a registered Trade Mark

IMIDOX Inspuiting
Reg. No. G3257 Wet 36/1947

DOSIS FORMAAT

Inspuitbare Oplossing

SAMESTELLING

Elke 1 ml bevat 120 mg imidokarbdipropionaat ekwivalent aan 85 mg per ml imidokarb.

INDIKASIES

Imidox genees rooiwater (Babesiose) en bosluigsiekte (Anaplasrose) in beeste. Dit kan in beeste gebruik word in die voorkoming van Asiatiese rooiwater vir tot 4 weke en Afrika rooiwater vir tot 8 weke. Imidox is ook aangedui vir die behandeling van Babesiose in perde en honde.

BERGINGS INSTRUKSIES

Stoor tussen 2 en 8 °. Moet nie vries nie. Besekrm teen lig.

Gebruik die inhoud van die fles binne 28 dae na die eerste produk onttrekking uit fles, vernietig alle ongebruikte produk.

WAARSKUWINGS

Moet nie diere slag vir menslike gebruik binne 28 dae na laaste behandeling.

Moet nie in lakterende koeie waar die melk of melk produkte vir menslike gebruik bestem is gebruik nie.

Hou buite bereik van kinders en oningeligte persone en diere.

Moet nie voorgeskrewe dosis oorskry nie.

Moet nie die produk na die verval datum gebruik nie, dit mag onaktief of skadelik vir die dier wees.

Swelling van die inspuitplek mag voorkom in sekere diere. Dit is van verbygaande aard en sal verdwyn sonder dat absess gevorm word.

Speekselvloeie mag waargeneem word na behandeling.

Beskerm teen lig.

Behandeling van oordosering is simptome en ondersteunend.

Indien vergifting plaasvind raadpleeg 'n geneeshere of professionele gesondheidswerker.

Alhoewel hierdie produk onder 'n wye verskeidenheid van toestande getoets is, mag die faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwitting die registrasiehouer.

VOORSORGMATREËLS

Verhoed binnearse toediening.

Die inspuitplek moet deeglik ontsmet word voor inspuiting.

Raak ontslae van leë houers deur dit in papier toe te draai en in vullis houer te plaas.

Weggoobare naalde moet onmiddellik in 'n vooraf bestemde houer wat duidelik gemerk is geplaas word.

DOSIS

BEESTE

Terpie van babesiose: 1 ml per 100 kg liggamsmassa per onderhuidse of binnespiers inspuiting. In baie erge gevalle mag 'n tweede inspuiting na 24 uur weer nodig wees.

Chemoprofilakse van bees babesiose: 2.5 ml per 100 kg liggamsmassa onderhuids of binnespiers. Die profilaktiese periode vir *Babesia bovis* is tot 4 weke en vir *Babesia bigemina* tot 8 weke. Onder veldtoestande is dit onder sekere omstandighede moontlik, bv. Met 'n hoë daging dat uitbrake van *B. bovis* mag plaasvind so gou as 18 dae na die profilaktiese toediening van Imidox. Immuniteit ontwikkel as behandelde diere gedaag word in die profilaktiese periode. Moet nie die dosis binne 4 weke herhaal nie.

Terapie van Anaplasrose: 2.5 ml per 100 kg liggaamsmassa onderhuids of binnespiers.

PERDE

Perde babesiose: *B. caballi*: 2 ml per 100 kg liggaamsmassa binnespiers. *B. equi*: 2 ml per 100 kg liggaamsmassa binnespiers. Twee behandelings binne 24 uur mag nodig wees.

HONDE

Honde babesiose: 0.5 ml per 10 kg liggaamsmassa met onderhuidse toediening.

GEBRUIKSAANWYSINGS

Steriliseer alle inspuit apparaat deur dit te kook (of soortgelyk) voor gebruik. Verhoed die gebruik van sterk ontsmettingsmiddels op spuite en naalde.

Onderhoue higiëne te alle tye.

Hou naalde skerp en skoon. Vervang gereeld.

Gebruik so kort naald as moontlik (moet nie 15 mm oorskry nie).

Waar moontlik moenie diere in nat weer of stof toestanded behandel nie.

Hierdie produk moet slegs onder die vel toegedien word, verkieslik hoog teen die nek agter die oor.

FARMAKOLOGIESE AKSIE

Imidokarbdipropionaat is 'n derivaat van die karbanieliede antiprotosoïese middels. Alhoewel die presiese metode van aksie van die middel onbekend is, is dit moontlik dat meganiese inmenging met die sellulêre herstel en replikasie plaasvind deur binding met die DNA. Imidokarb is hoogs doeltreffend teen besmettings veroorsaak deur *Babesia* en *Anaplasma spp.*

Babesiose, ook bekend as rooiwater word veroorsaak deur bosluis oordraagbare protosoïese parasiete van die genus *Babesia*. Babesiose word gekenmerk deur koors, anemie, geelsug en hemoglobienurie. Dit is 'n wydverspreide siekte, meer algemeen in tropiese gebiede waar die bees bosluis *Boophilus decoloratus* algemeen voorkom. Die mees belangrike parasiete wat babesiose in beeste veroorsaak is *Babesia bovis* en *Babesia bigemina*.

In endemiese gebiede word kalwers op 'n jong ouderdom met *Babesia* besmet, maar die besmetting manifesteer nie in 'n kliniese geval nie weens natuurlike weerstand. Diere wat vroeg besmet word, is draers van die besmetting en bly immuun teen die kliniese siekte vir solank as die besmetting duur. Herbesmetting vind gereeld plaas in endemiese gebiede. Sonder besmetting word immuniteit binne 'n paar maande verloor met gevolglike kliniese gevalle.

Kliniese siekte toestande ontstaan meestal wanneer:

- i. vatbare diere vervoer word van nie endemiese gebiede na endemiese gebiede
- ii. kontak ontstaan tussen besmette en nie-besmette diere
- iii. epidemies ontstaan nadat die besmetting na nie-endemise gebiede verskuif is, of 'n skielike verhoging in die bosluispopulasie ontstaan het onder gunstige omgewings faktore
- iv. die bosluis oordraging populasie neem af, agv. veranderde weersomstandighede of deur doeltreffende bosluisbeheer maatreëls wat tot gevolg het dat herbesmetting afneem wat dan tot die verlaging van immuniteit aanleiding gee.

Behandeling van kliniese gevalle van babesiose met **Imidox** is mees effektief wanneer diere vroeg in die verloop van die siekte behandel word, in kombinasie met ondersteuningsbehandeling soos die verskaffing van skaduwee. Wanneer die siekte ernstig is, mag opvolg behandeling met **Imidox** nodg wees na 24 uur.

Sterilisering van die besmetting met **Imidox** ontstaan met totale eliminering van die Babesia parasiet uit draer diere. Eliminering van draers is nodig waar diere uit endemiese gebiede na nie-endemiese gebiede geskuif word wat andersins sal veroorsaak dat vatbare diere besmet word.

Voorkoming van Babesia besmetting mag verkry word deur vatbare diere met **Imidox** te behandel voordat hulle na 'n endemiese gebied verskuif word. Oor 'n periode van tyd sal die vlak van imidokarb in die diere se liggaam afneem wat 'n klein hoeveelheid parasiete sal toelaat om die diere se sisteem te infekteer, terwyl die diere nog deur die middel beskerm word. Die resultaat is die ontwikkeling van immuniteit teen die siekte sonder voorkoms van enige kliniese tekens. Indien daar geen blootstelling aan besmetting gedurende die afname van imidokarb in die diere is nie, sal die diere vatbaar word vir die kliniese siekte toestand. 'n Enkel dosis van **Imidox** sal beskerming teen besmetting bied vir tot 4 weke. **Imidox** is doeltreffend vir die beskerming van vatbare diere teen babesiose waar daar deur 'n endemiese gebied beweeg moet word. Uitbrake kan beheer word deur voorkomingsdosisse van **Imidox** aan alle diere wat aan die siekte blootgestel was toe te dien, daar moet egter opgelet word dat enting op 'n later stadium noodsaaklik is.

Anaplasmose is 'n bosluisoorgedraagde siekte veroorsaak deur die rickettsi organisme *Anaplasma marginale* wat die rooi bloedselle parasiteer. Die verloop van die siekte kan vir maande voortduur. Die graad van siekte na besmetting verhoog in ouer diere, en bereik tot 50 % mortaliteit in vatbare volwasse beeste.

Kliniese tekens van anaplasmose is akute bloedarmoede met koors, vergeling van oogvliese en vermaering. Afname in melk produksie en aborties is algemeen. Die kliniese tekens van anaplasmose en babesiose is baie dieselfde, maar die dosis vlak in die behandeling van die siektes verskil. Dit is daarom belangrik dat bloedsmerie voorberei word van geïdentifiseerde gevalle, vir laboratorium ondersoek om sodoende tussen die siektes te onderskei.

Imidox is 'n effektiewe behandeling vir anaplasmose teen die aanbeveelde dosis valk. Ondersteunende behandelingsterapie moet ingestel word, dit sluit in verskaffing van skadu met genoegsaam voer en water. In erge gevalle mag bloedoortapping benodig word. Diere wat herstel het moet vir nog 4 weke gemonitor word na die laaste behandeling, aangesien herbehandeling nodig mag wees ingeval 'n insinking voorkom. Om die risiko van oordraging van die siekte te verlaag, moet die kudde verskeie kere met bosluis dipmiddels gedip word om bosluise te beheer.

AANBIEDING

Imidox Injection is beskikbaar in 20 ml donkerglas of 100 ml donker poli-etileen multi dosis flesse in kartonne.

REGISTRASIEHOUER

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