

FOR ANIMAL USE ONLY

ROTAVEC® CORONA

Reg. No. G2955 (Act 36/1947)

Namibia Reg. No. V07/24.4/747 NS0

Only for use by or under the supervision of persons registered in terms of or authorized in terms of section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act no. 19 of 1982).

INDICATIONS

For the active immunisation of pregnant cows and heifers to raise antibodies against *E. coli* adhesion F5 (K99) antigen, rotavirus and coronavirus. While calves are fed colostrum from vaccinated cows during the first 2 to 4 weeks of life, these antibodies have been demonstrated to:

- Reduce the severity of diarrhoea caused by *E. coli* F5 (K99).
- Reduce the incidence of scours caused by rotavirus.
- Reduce the shedding of virus by calves infected with rotavirus or coronavirus.

COMPOSITION

Each 2 ml contains:

Inactivated bovine rotavirus	10 ^{7.6} to 10 ^{7.9} TCID ₅₀
Inactivated coronavirus	150 to 230 ELISA units
Inactivated <i>E. coli</i> K99 antigens	100 to 120 units

Adjuvant: aluminium and light mineral oil/emulsifier.

Preservative: thiomersal 0,0006 % w/v.

STORAGE

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

WARNINGS

- **Withdrawal period:** None.
- Vaccinate only healthy animals.
- Do not mix **Rotavec® Corona** with any other veterinary medicinal product.
- No information is available on the concurrent use of **Rotavec® Corona** with any other vaccines. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with **Rotavec® Corona**.
- Ensure that vaccination equipment and hands are clean before use.
- It is good vaccination practice when handling the vaccine to avoid contact with the eyes, hands and clothing.
- Partly used containers of the vaccine should be discarded within 8 hours of opening. Destroy any unused vaccine, empty vaccine vials, needles etc. in accordance with local waste disposal regulations.
- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- Although this vaccine 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.

Special precautions to be taken by the person administering Rotavec® Corona to animals

Rotavec® Corona contains mineral oil. If you are accidentally injected with **Rotavec® Corona**, seek prompt medical advice even if only a very small amount is injected and take

the package insert with you and show to the doctor. If pain persists for more than 12 hours after medical examination, seek medical advice again.

Note to doctor

Rotavec® Corona contains mineral oil. Even if small amounts have been self-injected, it can cause intense vascular spasm which may, for example result in ischemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of a finger pulp or tendon sheaths.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

Shake well before use.

Dose

- Cows and heifers: 2 ml intramuscular. The recommended injection site is the side of the neck.
- A single injection should be given during each pregnancy at any time between 12 weeks and 3 weeks before calving is expected.
- Syringes and needles should be sterilised before use and the injection should be made through an area of clean, dry skin taking precautions against contamination.

IMMUNITY

In any animal population there may be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct storage and administration of the vaccine, together with the animal's ability to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, the presence of maternally-derived antibodies, nutritional status, concurrent drug therapy and stress.

Colostrum feeding

Protection of calves depends on the physical presence of colostrum antibodies (from vaccinated cows) within the gut for the duration of the first 2 to 3 weeks of life until calves develop their own immunity. Thus, it is essential to ensure adequate colostrum feeding for the whole period to maximise the efficacy of vaccination.

All calves must receive adequate colostrum from their dams within 6 hours of birth. Suckled calves will continue to receive adequate colostrum naturally by feeding from vaccinated cows.

In the dairy herd colostrum/milk from the first 6 to 8 milkings of vaccinated cows should be pooled. The colostrum may be stored below 20 °C but should be used as soon as possible as immunoglobulin levels may fall by up to 50 % after storage for 28 days. Where possible, storage at 4 °C is recommended. The calves should then be fed on this pool at the rate of 2½ to 3½ l per day (according to body size) for the first 2 weeks of life.

Optimal results will be obtained if a whole herd cow vaccination policy is adopted. This will ensure that the level of infection and consequent virus excretion in calves is kept to a minimum and consequently the overall level of disease challenge on the farm is kept to a minimum.

Further information

Calf diarrhoea is a complex disease of which rotavirus, coronavirus and *E. coli* are 3 of the most important causal agents in calves in the first few weeks of life. The vaccine will aid in reducing the incidence of scours caused by rotavirus, coronavirus and *E. coli* where these are the sole aetiological agents. The vaccine provides no protection against *cryptosporidia* (for which there is currently no vaccine), but often mixed infections occur, and it may help to some degree by providing protection against any concurrent rotavirus, coronavirus and *E. coli* F5 (K99) infections. The presence of each agent can be confirmed by laboratory sampling of fresh faeces samples (not swabs) taken directly from calves before any treatment. As the level of passive protection induced by the vaccine is not absolute, coronavirus and rotavirus infections may occur in calves from vaccinated dams but will be contained whilst the calf is mounting its own active immune response against the viruses.

The F5 (K99) antigen enables *E. coli* to adhere to the calf's small intestine where the bacteria multiply rapidly and produce toxins leading to scours, typically in the first few days of life. Specific antibodies can inhibit *E. coli* sticking to the gut wall and thereby their ability to cause diseases. The *E. coli* F5 (K99) antigen in **Rotavec® Corona** promotes the production of antibodies in colostrum and milk.

VACCINATION REACTION

- The oil adjuvant provides the convenience of a single shot vaccine and has been carefully chosen to minimise any consequent side effects. It may produce a detectable swelling at the site of injection in some animals. The injection site reaction gradually reduces in size until it is no longer detectable, usually 14 to 21 days after treatment.
- As with all vaccines occasional hypersensitivity reactions may occur. In such cases, consult your veterinarian immediately.

PRESENTATION

Glass or plastic vials, containing 40 ml (20 doses). Closed with a rubber stopper and an aluminium seal, packed in a cardboard box.

MANUFACTURER

Intervet International B.V.
35 Wim de Körverstraat, Boxmeer
The Netherlands

REGISTRATION HOLDER

Intervet South Africa (Pty) Ltd.
20 Spartan Road
Spartan, 1619, RSA
Tel: +27 (0) 11 923 9300
Fax: +27 (0) 11 392 3158
www.msd-animal-health.co.za

DATE OF PUBLICATION OF THIS PACKAGE INSERT

12 April 2010

SLEGS VIR DIEREGERBUIK

ROTAVEC® CORONA

Reg. Nr. G2955 (Wet 36/1947)

Namibië Reg. Nr. V07/24.4/747 NS0

Slegs vir gebruik deur of onder die toesig van persone geregistreer of daartoe gemagtig in terme van artikel 23 (1) (c) van die Wet op Veterinêre en Para-Veterinêre Beroepe, 1982 (Wet Nr. 19 van 1982).

INDIKASIES

Vir die aktiewe immunisering van dragtige koeie en verse vir die vermeerdering van teenliggame teen *E. coli* hegting F5 (K99) antigeen, rotavirus en koronavirus. Dit bewys dat indien kalwers gedurende die eerste 2 tot 4 weke kolostrum ontvang van ingeënte koeie hierdie teenliggame die volgende bewerkstellig:

- Vermindering van hewigheid van diarree veroorsaak deur *E. coli* F5 (K99).
- Vermindering van die voorkoms van diarree veroorsaak deur rotavirus.
- Vermindering van virusuitskeiding deur kalwers aangetas met rotavirus of koronavirus.

SAMESTELLING

Elke 2 ml bevat:

Geïnaktiveerde beesrotavirus 10^{7,6} tot 10^{7,9} TCID₅₀
Geïnaktiveerde koronavirus 150 tot 230 ELISA eenhede
Geïnaktiveerde *E. coli* K99 antigene 100 tot 120 eenhede
Adjuvantium: aluminium en ligte mineraalolie/emulsifiseerder
Preserveermiddel: tiomersalaat 0,0006 % w/v.

BERGING

- Berg tussen 2 °C en 8 °C.
- Moenie vries nie.
- Beskerm teen sonlig.

WAARSKUWINGS

- **Onttrekkingsperiode:** Geen.
- Slegs gesonde diere mag ingeënt word.
- **Rotavec® Corona** moenie met enige ander veteriner medisyne gemeng word nie.
- Geen inligting is beskikbaar oor die gelyktydige gebruik van **Rotavec® Corona** met ander entstowwe nie. Dit word dus aanbeveel dat geen ander entstof toegedien word binne 14 dae voor, of na inenting met **Rotavec® Corona** nie.
- Sorg dat alle inentingstoerusting en hande skoon is voor gebruik.
- Dit is goeie inentingspraktyk om kontak met die oë, hande en klere te vermy wanneer die entstof hanteer word.
- Gedeeltelik gebruikte entstofhouers moet vernietig word binne 8 ure nadat dit oopgemaak is. Vernietig alle ongebruikte entstof, leë entstofhouers, naalde ens. soos voorgeskryf deur plaaslike afvalbestuursregulasies.
- HOU BUITE DIE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.
- Alhoewel hierdie entstof onder 'n wye verskeidenheid toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwittig die registrasiehouer.

Spesiale voorsorgmaatreëls wat geneem moet word deur die persoon wat Rotavec® Corona vir diere toedien

Rotavec® Corona bevat mineraalolie. As u per ongeluk u self met **Rotavec® Corona** inspuit, moet mediese advies vinnig gekry word, selfs al is dit net 'n baie klein hoeveelheid wat ingespuut is. Neem die voubiljet saam na die geneesheer. Indien die pyn voortduur vir meer as 12 ure na die mediese ondersoek, kry weer mediese hulp.

Nota aan geneesheer

Rotavec® Corona bevat mineraalolie. Selfs al is 'n klein hoeveelheid toegedien, kan self-inspuiting met hierdie produk hewige vasculêre spasma veroorsaak wat byvoorbeeld kan lei tot iskemiese nekrose en selfs die verlies van 'n vingerlit. Kundige, VINNIGE, chirurgiese aandag mag vereis word en vroeëre insnyding en irrigasie van die toedieningsarea mag nodig wees, veral waar daar vingerlitweefsel of 'n sening betrokke is.

GEBRUIKSAANWYSINGS - GEBRUIK SLEGS SOOS AANGEDUI

Skud goed voor gebruik.

Dosis

Koeie en verse : 2 ml binnespiers. Die aanbevole inspuitingsplek is aan die kant van die nek. 'n Enkele inspuiting moet op enige tyd tussen 12 weke en 3 weke voor die verwagte kalwing, gedurende elke dragtigheid, toegedien word.

Om voorsorg teen kontaminasie te tref moet spuite en naalde voor gebruik gesteriliseer word en die inspuiting moet toegedien word op 'n skoon, droë vel.

IMMUNITEIT

In enige dierepopulasie mag daar 'n klein aantal diere wees wat nie voldoende reageer op inenting nie. Suksesvolle inenting is afhanklik van die regte berging en toediening van die entstof, asook die dier se vermoë om te reageer op die inenting. Dit kan deur verskeie faktore beïnvloed word bv. genetiese samestelling, onderliggende infeksie, ouderdom, die teenwoordigheid van moederteenliggame, voedingstatus, medikasie wat gelyktydig toegedien word en stres.

Kolostrumvoeding

Vir die eerste 2 tot 3 weke na geboorte is kalwers afhanklik van die teenwoordigheid van kolostrumteenliggame (vanaf ingeënte koeie) in die dermkanaal vir hulle immuniteit. Kalwers begin slegs 3 weke na geboorte hul eie immuniteit ontwikkel. Dit is dus noodsaaklik om voldoende kolostrumvoeding vir die hele periode te verseker om die effektiwiteit van die inenting te optimaliseer.

Al die kalwers moet binne 6 ure na geboorte genoeg kolostrum van die moeder ontvang. Soogkalwers sal aanhou om natuurlike genoegsame kolostrum te ontvang deur te soog aan ingeënte koeie.

In die melkkudde behoort die kolostrum/melk van die eerste 6 tot 8 melkings van ingeënte koeie versamel te word. Die kolostrum kan geberg word onder 20 °C, maar moet so gou as moontlik gebruik word, want die immunoglobulienvlakke mag met tot 50 % val na berging langer as 28 dae. Waar moontlik, word berging teen 4 °C aanbeveel. Die kalwers word dan vir die eerste 2 weke na geboorte gevoed met hierdie kolostrum teen 'n tempo, van 2½ tot 3½ l per dag, afhangende van grootte.

Optimale resultate sal verkry word as 'n beleid ingestel word om al die koeie in die kudde in te ent.

Dit sal verseker dat die vlak van infeksie en die gepaardgaande virusuitskeiding in kalwers minimaal is en gevolglik sal die algemene vlak van uitdaging van die siekte op die plaas tot 'n minimum beperk word.

Verdere inligting

Kalfdiarree is 'n gekompliseerde siekte waarvan rotavirus, koronavirus en *E. coli*, 3 van die belangrikste veroorsakende agente is in kalwers gedurende die eerste paar weke na geboorte. Die entstof sal help om die voorkoms van diarree veroorsaak deur rotavirus,

koronavirus en *E. coli* waar hulle die enigste etiologiese agente is, te voorkom. Die entstof bied geen beskerming teen *cryptosporidia* (waarvoor daar huidiglik geen entstof is nie), maar verskeie infeksies kom gereeld saam voor en dit mag tot 'n mate help deur beskerming te verskaf teen enige gelyktydige rotavirus, koronavirus en *E. coli* F5 (K99) infeksies. Die teenwoordigheid van elke agent kan vasgestel word deur laboratoriummonsters van vars ontlasting (nie deppers) te neem by kalwers voor enige behandeling. Omdat die vlak van passiewe beskerming bewerkstellig deur die entstof nie onbeperk is nie, mag infeksies van die koronavirus en rotavirus in kalwers van ingeënte koeie voorkom, maar dit sal onder beheer gehou word terwyl die kalf sy eie aktiewe immuunreaksie teen die virusse opbou. *E. coli* heg d.m.v. die F5 (K99) antigeen aan die oppervlak van die dunderm. Hier is die organisme in staat om te vermenigvuldig en toksiene te produseer wat diarree veroorsaak. Hierdie toestand kom tipies voor in die eerste paar dae na geboorte. Spesifieke teenliggame teen *E. coli* wat aan die derm vasklou, inhibeer die organisme se vermoë om siektes te veroorsaak. Die *E. coli* F5 (K99) antigeen in **Rotavec® Corona** stimuleer die produksie van teenliggame in kolostrum en melk.

INENTINGSREAKSIES

- Die olie-adjuvant verskaf die gerief van 'n eenmalige toediening van die entstof en is sorgvuldig gekies om die gepaardgaande neue-effekte te minimaliseer. Dit mag in sekere diere 'n merkbare swelling by die plek van inenting veroorsaak, wat dan gewoonlik na 14 tot 21 dae na behandeling geleidelik kleiner word, totdat dit naderhand nie meer opmerkbaar is nie.
- Soos met alle entstowwe mag toevallige hipersensitiwiteitsreaksies voorkom. In sulke gevalle, raadpleeg u veearts dadelik.

AANBIEDING

Glas- of plastiekflessies wat 40 ml (20 dosisse) bevat. Toegemaak met 'n rubberprop en 'n aluminiumseël, in 'n kartonhouer verpak.

VERVAARDIGER

Intervet International B.V.
Wim de Körverstraat 35, Boxmeer
The Netherlands

REGISTRASIEHOUER

Intervet South Africa (Pty) Ltd.
Spartanweg 20
Spartan, 1619, RSA
Tel: +27 (0) 11 923 9300
Faks: +27 (0) 11 392 3158
www.msd-animal-health.co.za

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

12 April 2010



