

FOR ANIMAL USE ONLY

RESPIRAVAX

Reg. No. G3867 Act 36/1947

Namibia Reg. No V10/24.4/719 NS0

INDICATIONS

Respiravax is an inactivated vaccine for the prophylactic immunisation of calves and pregnant cattle as an aid in reducing or preventing bovine respiratory disease caused by bovine herpes virus 1 (IBRV), bovine viral diarrhoea virus type 1 (BVDV), parainfluenza virus type 3 (PI₃V) and *Mannheimia (Pasteurella) haemolytica*.

COMPOSITION

Respiravax is a ready-to-use aqueous vaccine containing inactivated BHV1 (IBR), PI₃ and BVD type 1 viruses, as well as a leukotoxin-containing cell-free supernatant of *Mannheimia haemolytica*, adsorbed onto alhydrogel. Viruses are propagated in tissue culture, inactivated with formaldehyde and diluted to 10⁶ TCID₅₀ for IBR and PI₃ and 10⁵ TCID₅₀ for BVDV per 1 ml dose. The leukotoxin component is a dilution of the cell-free supernatant of a three-hour fermentation culture. The vaccine contains no preservative, other than formaldehyde.

STORAGE

- Store between 2 °C and 8 °C.
- Do not freeze.
- Avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator.
- Protect from direct sunlight.

WARNINGS

- **Withdrawal period:** Do not vaccinate within 21 days prior to slaughter.
- Vaccinate healthy animals only.
- Anaphylactic reactions, although rare, may occur.
- Should an allergic reaction occur, intramuscular adrenalin should be administered.
- Do not store partially used containers for future use and use the entire contents within 10 hours of opening.
- Destroy any unused vaccine and dispose of all vaccine containers according to local waste disposal regulations, after vaccination.
- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- Although this vaccine has been extensively tested under a variety of conditions, failure thereof may ensue for a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

- Follow aseptic procedures. Ensure that vaccination equipment (syringes, needles etc) is clean and sterile before use.
- Ensure that all equipment is kept clean and sterile during vaccination.

- Avoid intravenous injection.
- Keep the vaccine cool and avoid exposure to direct sunlight and high temperatures during inoculation.
- When handling vaccine, it is good vaccination practice to avoid contact with the eyes, hands and clothing.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED
MAY BE USED DURING PREGNANCY AND LACTATION.

Vaccinate only healthy cattle.

Suspend the contents of the vial by gentle end-over-end mixing the vial at least 6 times.

Dosage

Inject 1 ml per animal subcutaneously.

Recommendations for use

- Vaccinate pregnant cows 6 to 8 weeks before calving. Cows that have not previously been vaccinated with **Respiravax** should receive a booster dose (1 ml) after 4 weeks, i.e. 3 to 4 weeks before calving.
- Calves from vaccinated cows should be vaccinated from 3 months of age.
- Calves from unvaccinated cows may be vaccinated at any age.
- A booster vaccination should be given after 4 weeks and then annually.
- Immunity starts to develop about 10 days after immunisation and animals should be protected after 3 weeks (complete protection cannot be guaranteed in all animals).

PRESENTATION

Vials containing 10 ml (10 doses), 20 ml (20 doses) and 100 ml (100 doses).

MANUFACTURER

Design Biologix CC
Meiring Naude Street
Lynnwood, Pretoria

REGISTRATION HOLDER

Intervet South Africa (Pty) Ltd.
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SLEGS VIR DIEREGERBRUIK

RESPIRAVAX

Reg. No. G3867 Wet 36/1947

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INDIKASIES

Respiravax is 'n geïnaktiveerde entstof vir die inenting van kalwers en dragtige koeie om bees respiratoriese siekte veroorsaak deur bees herpes virus 1 (IBRV), bees virale diarree virus tipe 1 (BVDV), parainfluenza virus 3 (PI₃V) en *Mannheimia (Pasteurella) haemolytica*, te verminder of te voorkom.

SAMESTELLING

Respiravax word gereed vir gebruik voorsien. Dit bevat chemies geïnaktiveerde BHV1 (IBR), BVD tipe 1 en PI₃ virusse, sowel as 'n leukotoksien-bevattende selvrye supernatant van *Mannheimia haemolytica*, geadsorbeer op alhidrojel. Virusse word in weefselkultuur vermeerder, geïnaktiveer met formaldehyd en verdun na 10⁶ TCID₅₀/dosis vir BHV1, PI₃V en 10⁵ TCID₅₀/dosis vir BVDV. Die leukotoksien komponent is 'n verdunning van die selvrye supernatant van 'n drie-uur fermentasiekultuur. Die entstof bevat geen preserveermiddels, behalwe formaldehyd.

BERGING

- Berg tussen 2 °C tot 8 °C.
- Moenie vries nie.
- Vermoed langdurige en herhaalde blootstelling aan hoë omgewingstemperature nadat die entstof uit die yskas gehaal is.
- Beskerm teen direkte sonlig.

WAARSKUWINGS

- **Onttrekkingsperiode:** Moenie inent binne 21 dae voor slagting nie.
- Ent slegs gesonde diere.
- Anafilaktiese reaksies kan voorkom, alhoewel skaars.
- Indien 'n allergiese reaksie voorkom, behoort binnespiers adrenalin toegedien word.
- Gedeeltelik gebruikte houers moet nie vir latere gebruik geberg word nie. Nadat die entstof oopgemaak is, moet die inhoud binne 10 ure gebruik word.
- Vernietig enige ongebruikte entstof en alle entstof houers na inenting in ooreenkoms met plaaslike afvalbestuursregulasies.
- HOU BUITE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.
- Alhoewel hierdie entstof deeglik onder 'n verskeidenheid toestande getoets is, mag dit faal vir verskeie redes. Indien dit vermoed word, raadpleeg u veearts en verwittig die registrasiehouer.

VOORSORGMAATREËLS

- Volg aseptiese prosedures. Maak seker dat alle inentingstoerusting (spuite, naalde ens) skoon en steriel is, voor gebruik.
- Sorg dat alle toerusting skoon en steriel gehou word gedurende inenting.
- Hou die entstof koel en vermoed blootstelling aan hoë temperature en direkte sonlig gedurende inenting.
- Dit is goeie inentingspraktyk om kontak met die oë, hande en klere te vermoed wanneer entstowwe hanteer word.

GEBRUIKSAANWYSINGS - GEBRUIK SLEGS SOOS AANGEDUI
DIE ENTSTOF IS VEILIG VIR GEBRUIK IN DRAGTIGE OF LAKTERENDE BEESTE.
Ent slegs gesonde diere.
Meng die inhoud deur die houer ten minste 6 keer om en terug te dop.

Dosis

Ent 1 ml per dier onderhuids

Aanbevelings vir gebruik

Ent dragtige koeie 6 tot 8 weke voor kalwing. Koeie wat nie voorheen met **Respiravax** geënt is nie, moet met 'n skraag dosis gespuit word (1 ml) na 4 weke, m.a.w. 3 tot 4 weke voor kalwing.

Kalwers van ingeënte koeie behoort vanaf ouderdom 3 maande ingeënt te word.

Kalwers van koeie wat nie ingeënt is nie, mag op enige ouderdom ingeënt word.

'n Skraag inenting behoort na 4 weke en dan jaarliks toegedien te word

Immuniteit begin na 10 dae ontwikkel en diere behoort na 3 weke beskerm te wees (die entstof kan nie volledige beskerming in alle diere waarborg nie).

AANBIEDING

Bottels wat 10 ml (10 dosisse), 20 ml (20 dosisse) en 100 ml (100 dosisse) bevat.

VERVAARDIGER

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REGISTRASIEHOUER

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