Paracox® 8

WITH SOLVENT FOR SPRAY-ON-CHICKENS

A simple idea for maximizing performance

Solvent for Spray-on Chickens

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Paracox® 8
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PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS - THE NEW STANDARD IN COCCIDIOSIS PREVENTION

- Paracox® 8 induces broad coccidiosis immunity, helping to prevent mortality and protect flock uniformity.
- Paracox® 8 with solvent for spray-on-chickens can be applied at the hatchery for **improved process control.**

UP TO
35%
INCREASED UPTAKE*

when using combined Paracox® 8 with solvent for spray-on-chickens compared with spray using water.

FEATURES & BENEFITS

Develops immunity against critical species of coccidiosis in chickens.

Spray-on-chickens using the new solvent means improved vaccination process control.

Paracox® 8 has the fastest onset of immunity in comparative trials with other attenuated coccidiosis vaccines.

*Data on file

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HOW PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS WORKS

Unique to the industry: a tenacious solvent that can be sprayed using spray equipment.

The solvent thins with the shear force of spray, and resumes its original form on the chicks to enhance preening.

Presented as a sterile, viscous, red, semi-opaque, liquid for use with 1000 or 5000 dose packs of Paracox® 8 vaccine.

The high viscosity liquid clings to feathers longer to enhance preening and vaccine uptake.

PARACOX® 8 USE CLAIMS

SPRAY ON FEED

MIX IN DRINKING WATER

NEW!
SPRAY-ON-CHICKENS USING SOLVENT

Paracox® 8
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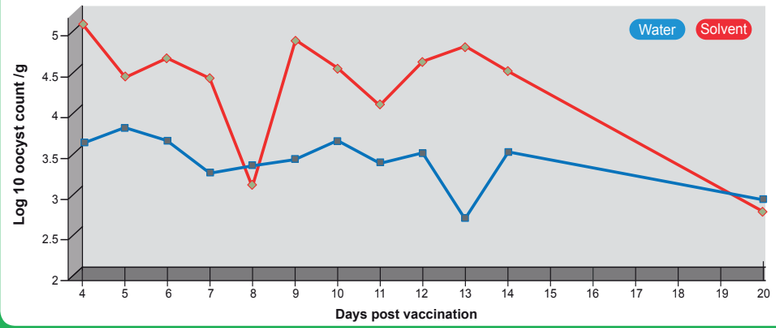
PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS TRIAL DATA

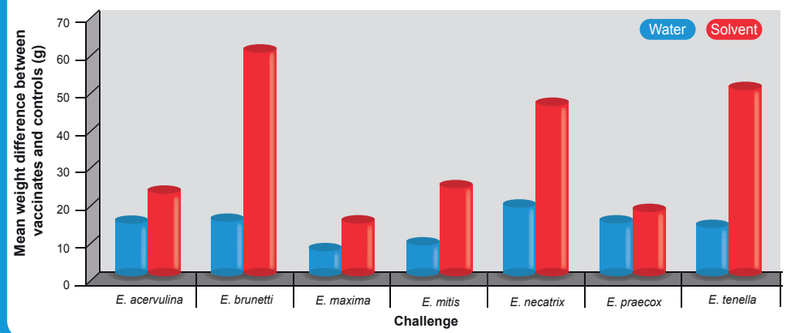
DOES SOLVENT FOR SPRAY-ON-CHICKENS ENHANCE VACCINE UPTAKE?

POST VACCINAL SHEDDING WITH HATCHERY SPRAY APPLICATION



Higher oocyst output means more oocysts were successfully ingested.

DIFFERENTIAL 7-DAY WEIGHT GAIN (SOLVENT VS WATER) FOLLOWING CHALLENGE AT 21 DAYS OF AGE



CONCLUSION

Spray on chickens at day-old using the new solvent for spray-on-chickens compared with water results in:

✓ IMPROVED UNIFORMITY OF VACCINE TAKE

✓ HIGHER POST VACCINATION OOCYST OUTPUT RESULTING IN:

- Enhanced flock protection at onset of immunity (21d).
- Improved weight gain following challenge.
- Reduced lesion score following challenge.

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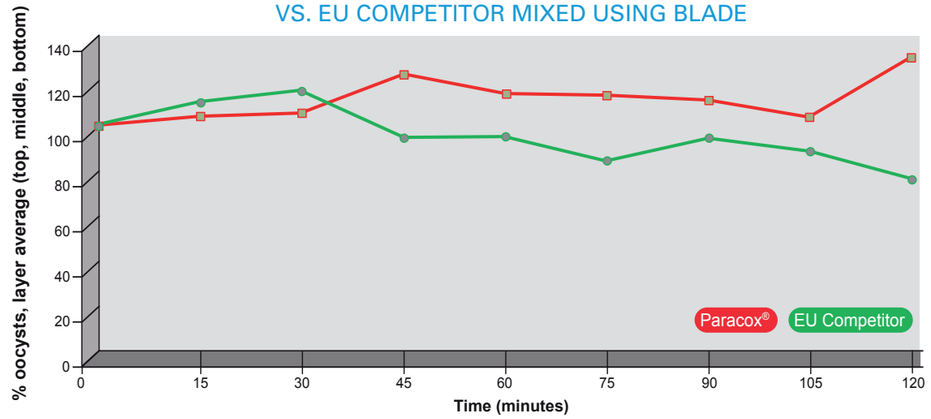
SOLVENT FOR SPRAY-ON-CHICKENS vs EU COMPETITOR COCCIDIOSIS GEL DILUENT

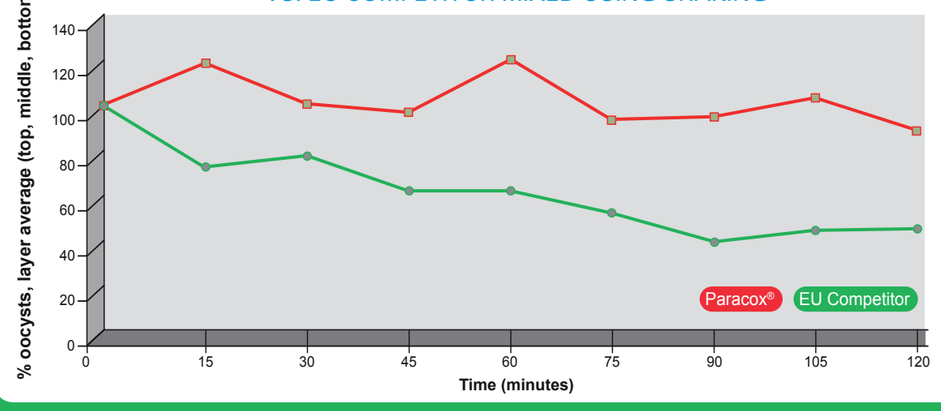
- Solvent for spray-on-chickens prevents oocyst settling compared to competitor.

NOT ALL GEL-TYPE SOLVENTS ARE ALIKE.
SOME ALLOW OOCYSTS TO SETTLE OVER TIME.

PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS VS. EU COMPETITOR MIXED USING BLADE



PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS VS. EU COMPETITOR MIXED USING SHAKING



- The overall reduction in oocysts (top + middle + bottom) in the EU competitor group is because oocysts are settling on the bottom of the container and cannot be picked up by the pipette, which is sampling the middle of each layer. Solvent for spray-on-chickens holds the oocysts in suspension, with each layer showing nearly 100% of the oocysts counted at Time Zero.

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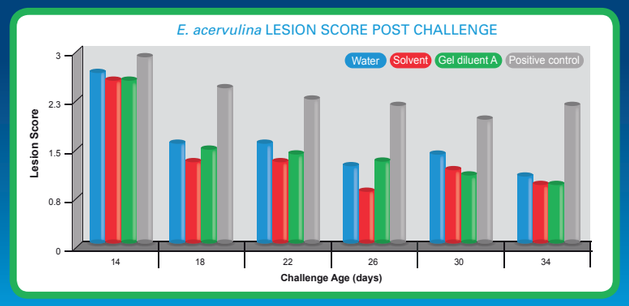
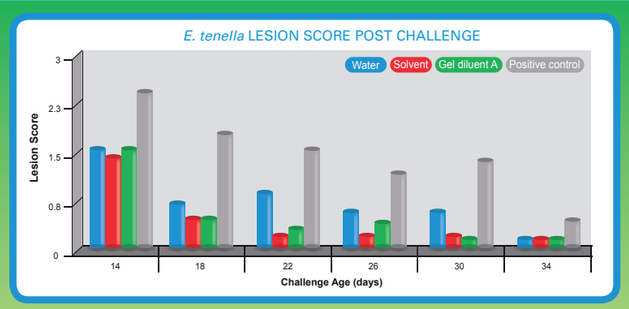
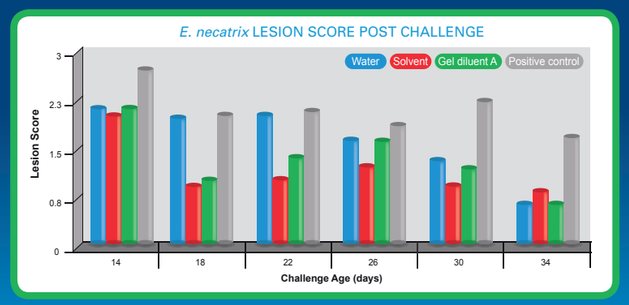
ONSET OF IMMUNITY: DILUENTS COMPARED BY ORAL DOSING (GAVAGE)

- Paracox® 8 was diluted and applied by oral gavage (direct application to mouth and crop) to day-old broiler chickens using each of three diluents:
  Water | Solvent for spray-on-chickens | Gel Diluent A with oral adjuvant
- Birds were placed in floor pens (50 birds per pen, 6 replicates per treatment) and allowed to develop immunity by recycling oocysts. Five birds per pen were weighed and challenged at 14, 18, 22, 26, 30 and 34 days with E. acervulina, E. tenella or E. necatrix and placed in a clean pen. At 6 days after challenge, the birds were weighed and all challenged birds were lesion scored.
- Oocyst output per gram of faeces was measured by pen beginning at day 7 and every three days until day 34.

LESION SCORE POST CHALLENGE







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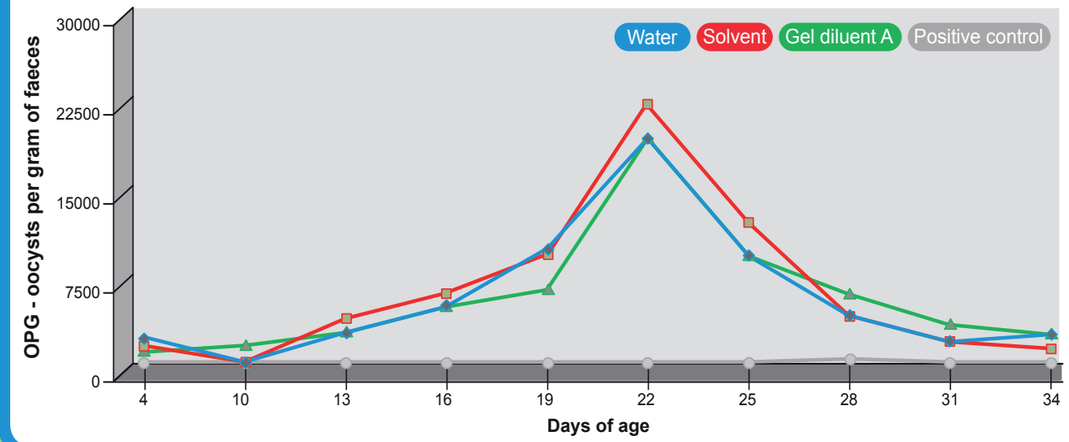
OOCYST SHEDDING PATTERNS



CONCLUSION

- ✓ PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS REACHED LOWER LESION SCORE EARLIER THAN WATER OR GEL DILUENT A, INDICATING FASTER ONSET OF IMMUNITY
- ✓ THICKER CONSISTENCY ENHANCES ONSET OF IMMUNITY EVEN WHEN ADMINISTERED BY GAVAGE
- ✓ ORAL ADJUVANT IN GEL DILUENT A DID NOT ENHANCE ONSET OF IMMUNITY
- ✓ PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS HAD SIGNIFICANTLY IMPROVED ONSET OF IMMUNITY COMPARED TO PARACOX® 8 SPRAY IN WATER
  - The lower lesion scores for Paracox® 8 with solvent for spray-on-chickens indicates stronger immunity at each time point

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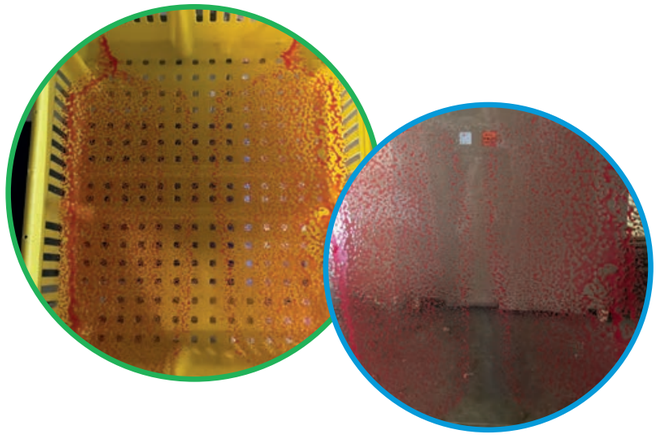
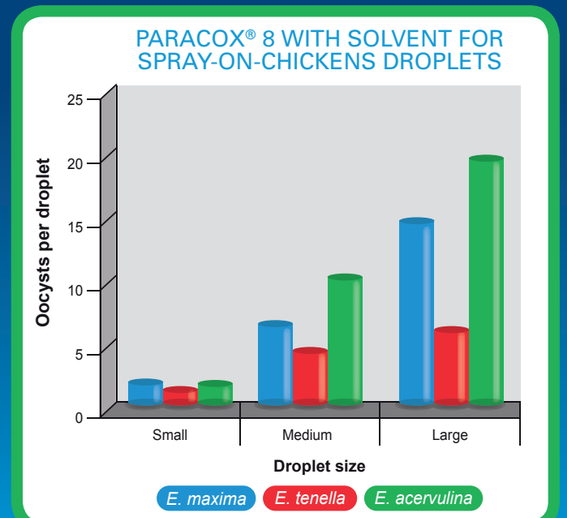
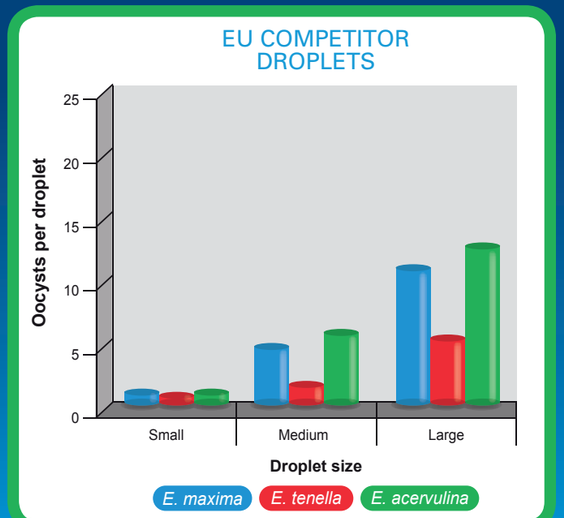
SOLVENT FOR SPRAY-ON-CHICKENS SPRAY APPLICATION

- Solvent for spray-on-chickens has unique shear properties that cause the gel to spray like a liquid, and then set up on the feathers once again as a gel form to enhance preening.
- The gel droplets eliminate fine droplets that can be carried away on air currents, as seen with water or the competitor gel spray.



PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS VS. EU COMPETITOR OOCYSTS PER DROPLET





WHAT IS MOST IMPORTANT? THE NUMBER OF OOCYSTS THAT REACH THE BIRDS!

- Paracox® 8 with solvent for spray-on-chickens shows proportional oocyst counts to droplet size, and maximizes the oocyst count on the chicks. When the identical vaccine and dose was sprayed with the competitor gel, fewer oocysts arrived on the plexiglass plate at bird level: some oocysts are lost to fine droplets carried out of the spray cabinet on air currents.

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PARACOX® 8 WITH SOLVENT FOR SPRAY-ON-CHICKENS ADMINISTRATION

METHOD OF APPLICATION

1 To mix Paracox® 8 with solvent for spray-on-chickens you will need: a large container, a small measuring vessel, a kitchen hand blender and of course the Paracox® sachet and the solvent.

Start by pouring the solvent into the large container - you will see the viscosity which is so essential in helping the vaccine to bead and cling to the chicks' feathers.

2 Next you will need to measure 50ml of water and add it to the empty solvent bottle. Shake vigorously and add to the large container - this ensures all of the solvent is used.

3 Then the Paracox® sachet should be added - it's important to shake the bag for 30 seconds before you add to the container.

4 Next you need to blend the Paracox® vaccine and solvent using the hand blender on a low speed setting for 2 minutes. This ensures good oocyst distribution.

The Paracox® and the solvent solution are now thoroughly mixed and ready for use in a spraying device such as a Spraycox cabinet.

DOSAGE

PARACOX® 8 VOLUME	ADDED SOLVENT + WATER	TOTAL VOLUME
5000 Dose Paracox® 8 (500ml sachet)	500ml Solvent + 50ml Water	1050ml
1000 Dose Paracox® 8 (100ml sachet)	100ml Solvent + 10ml Water	210ml

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MANAGEMENT OF COCCIDIOSIS VACCINATION

Coccidiosis immunity is developed through multiple exposures to the Eimeria parasite antigens.

The first critical step of coccidiosis vaccination is to ensure uniform uptake of a full dose of coccidiosis vaccine. This is best achieved at the hatchery, where processes are better controlled. Paracox® 8 with solvent for spray-on-chickens helps to ensure the best possible take when birds are vaccinated properly.

Unlike viral vaccines, coccidiosis vaccines are ‘self-boosting’; they recycle under the correct field conditions.

It is critical that coccidiosis-vaccinated birds continue to have access to their faeces containing shed oocysts until immunity is complete. When chicks ingest a coccidiosis vaccine, the sporulated oocysts break open and the parasites will infect the intestinal cells, completing multiple stages of the Eimeria life cycle.

After this initial life cycle, new oocysts are shed into the litter. To achieve immunity, the oocysts must become infective by sporulating in the litter, and the birds must ingest them to initiate the next life cycle. A third and sometimes a fourth or fifth life cycle must be completed to induce fully protective immunity against all Eimeria species.

Several factors interact under field conditions to speed or slow the onset of immunity.

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1. SPORULATION	2. OOCYST OUTPUT	3. BIRD DENSITY
The newly shed oocysts must sporulate to become infective.	Birds in a pullet house must be able to consume enough fully sporulated oocysts to initiate a secondary infection - they must have access to faeces - either on the floor or on paper.	Low bird density and dry house conditions can result in poor sporulation and reinfection rates.
This process requires oxygen, warmth and humidity.	Uneven sporulation and reinfection can result in incomplete immunity to some species or enable pathogenic wild strains to infect flocks.	Monitoring fecal oocyst counts during immunity development helps to identify potential problems.
Relative humidity of about 70% is recommended.	The precocious strains of Eimeria found in Paracox® do not induce coccidiosis. Recent studies at 40X dose yielded lesion scores for *E.tenella* of 0.1, *E. brunetti* of 0.1 and *E. necatrix* 0.0 using the Johnson and Reid scoring method.*	House environments differ: enlist the help of your MSD Animal Health representative to aid in monitoring and fine-tuning your pullet vaccination programme.
		It is important for all components of recycling to be balanced: environmental conditions for sporulation, oocyst output and bird stocking density. This ensures rapid and uniform development of immunity with coccidiosis vaccine.

*Data on file

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DATA SHEET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT PARACOX-8, suspension for oral suspension for chickens **2. QUALITATIVE AND QUANTITATIVE COMPOSITION** Per dose of 0.1 ml vaccine: Active substances: *Eimeria acervulina* HP...500 oocysts, *Eimeria brunetti*, HP...100 oocysts, *Eimeria maxima* CP...200 oocysts, *Eimeria maxima* MFP...100 oocysts, *Eimeria mitis* HP...1000 oocysts, *Eimeria necatrix* HP...500 oocysts, *Eimeria praecox* HP...100 oocysts, *Eimeria tenella* HP...500 oocysts Solvent for spray-on-chickens Excipients: Carminic acid (red colorant, E120), Xanthan gum (E415). For the full list of excipients, see section 6.1. **3. PHARMACEUTICAL FORM** Suspension for oral suspension. Vaccine: aqueous suspension. Solvent for spray-on-chickens: semi-opaque, red, viscous solution. **4. CLINICAL PARTICULARS 4.1 Target species** Chickens. **4.2 Indications for use, specifying the target species** Drinking water In chickens from 5 to 9 days of age, intended for living more than 10 weeks (breeders, laying hens, broilers ...): - active immunisation against coccidiosis caused by *E. acervulina, E. brunetti, E. maxima, E. mitis, E. necatrix, E. praecox et E. tenella*. Spray-on-chickens For the active immunisation of chickens against coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mitis, E. necatrix, E. praecox,* and *E. tenella*; - to reduce infection (oocyst excretion) with an OOI of 21 days for all strains, except *E. mitis*. - to reduce loss in weight with an OOI of 21 days for all strains, except *E. maxima*. DOI: at least 10 weeks for all strains. **4.3 Contraindications** Do not administer when chicken housing is not cleaned and litter removed between each rearing cycle. **4.4 Special warnings for each target species** Vaccinate only healthy animals. **4.5 Special precautions for use** Special precautions for use in animals Water and food provided to chickens before, during and after vaccination, must be free from anticoccidial agents or agents having anticoccidial activity. Ensure that all vaccination equipment is thoroughly cleaned before use according to usual practices of hygiene in poultry breeding: disassembly, cleaning and disinfection of syringes firstly, and of drinkers on the other hand, ending by a rinse with potable water. Do not use in dry drinkers. Chickens should be healthy and floor-reared (on litter). To ensure long-term immunity, it is necessary that the immunity produced by the medicinal product be boosted by a natural contact of the birds with coccidia in their environment. Any feed intake with anticoccidial activity, at any time after vaccination, may shorten the duration of immunity. This is especially important within 4 weeks following vaccination. Careful cleaning of buildings between each band of birds limits the number of persistent coccidia in areas and reduces the risk of early coccidiosis reached before the development of immunity. Special precautions to be taken by the person administering the veterinary medicinal product to animals. Drinking water: Birds must be thirsty by suppression of drinking water for about 1 to 2 hours prior to vaccination. The vaccine sachet should be thoroughly homogenized before use, by a vigorous handling without being brutal. The medicinal product contains xanthan gum which will aid the suspension of oocysts in the water providing the vaccine is delivered into each drinker through an automatic syringe equipped with the cannula included in the packaging. The syringe should be directed at an oblique angle to the surface of the water and stirred for the propulsion of the vaccine to enhance the distribution. The vaccine should not be administered in a large tank (end of building for example). It should be delivered in the drinkers themselves. Spray-on-chickens: For administration by spray on chickens the vaccine should be diluted using "Solvent for spray-on-chickens". **4.6 Adverse reactions (frequency and seriousness)** Not known. **4.7 Use during pregnancy, lactation or lay** Not applicable. **4.8 Interaction with other medicinal products and other forms of interaction** See section "Special precautions for use in animals". **4.9 Amounts to be administered and administration route** For oral administration to chickens from one day of age by spray on chickens or between 5 and 9 days of age via drinking water. Administration via drinking water Oral administration of 0,1 ml per chick in drinking water. - when all the drinkers in the house are bell-type with same size, the appropriate amount (in ml) of vaccine for delivery into each drinker is calculated thus: (Total number of chickens per house (or pen)/ Total number of drinkers per house (or pen)) x 0,1 - when the format of all the drinkers is heterogeneous, it is preferable to mix extemporaneously in one or several watering cans 5 ml of water and 0.1 ml of vaccine per bird, without exceeding this dilution, and to distribute the vaccine suspension in the empty drinkers. Administration via spray-on-chickens Vaccine should be delivered using a dose volume of 0.21 ml of diluted vaccine per bird using a coarse spray. Determine the delivery capacity of the spray device in terms of the volume delivered per 100 birds. Multiply this volume by 50 to give the total volume of diluted vaccine required for 5,000 doses (or by 10 for 1,000 doses). I.e. for the preparation of 5000 doses diluted vaccine, a total of 0.21 × 5000 = 1050 ml diluted vaccine is needed and is divided over the vaccine, solvent and water as below: 1. 500 ml Paracox-8 vaccine (1 sachet) 2. 500 ml Solvent (1 bottle) 3. Fill up to 1050 ml with water. The solvent contains red colouring agent and xanthan gum, both for better uptake. Water used for vaccine dilution should be fresh, cool and free of pollution. Take a clean container for vaccine preparation, add the solvent to the container and add the calculated amount of water in the container and mix solvent and water to an uniform solution. Shake and massage the 5000 dose (or 1000 dose) sachet of Paracox-8 vigorously for 30 seconds to ensure re-suspension of the oocysts. Add the entire contents of the sachet into the container with solvent and water, and mix thoroughly. Add the diluted vaccine to the applicator reservoir and spray evenly over the birds using a coarse spray. Ensure a controlled, even coverage of the total internal surface area of the box containing the chickens. Leave the birds in the box for at least 30 minutes in a well-lit area to allow time for the birds to preen. **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary** Severe overdose (x 10 or more) may lead to a temporary reduction in daily weight gain. **4.11 Withdrawal period** Not applicable. **5. IMMUNOLOGICAL PROPERTIES** Pharmacotherapeutic group: immunologicals for aves, domestic fowl, live parasitic vaccines, coccidia. ATCvet code: QI01AN01. PARACOX-8 is a live attenuated vaccine containing 8 different strains of Eimeria responsible for the main avian coccidiosis. **6. PHARMACEUTICAL PARTICULARS 6.1 List of excipients** Paracox-8, Xanthan gum, E415, Purified water Solvent for spray-on-chickens Carminic acid (red colorant, E120), Sodium chloride, Xanthan gum, E415, Water for injection **6.2 Incompatibilities** None known. Do not mix with any other veterinary medicinal product except the solvent for use for spray-on-chicken administration. **6.3 Shelf life** Paracox-8 Shelf-life of the veterinary medical product as packaged for sale: 28 weeks. Shelf life after dilution according to directions: 4 hours. Solvent for spray-on-chickens Shelf life as packaged for sale: 2 years. **6.4. Special precautions for storage** Paracox-8 Store in a refrigerator (2°C - 8°C). Protect from light. Do not freeze. Once broached, sachets must be disposed within 24 hours after use. Solvent for spray-on-chickens Store between 2-25°C. **6.5 Nature and composition of immediate packaging** Paracox-8 Polyethylene sachet. Solvent for spray-on-chickens Plastic PET vials closed with a rubber stopper and sealed with an aluminium cap. For administration by spray-on-chickens the suspension is supplied together with the appropriate volume of solvent (100 ml solvent for 1000 doses, 500 ml for 5000 doses). Pack size: 100 ml solvent, 500 ml solvent. **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products** Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. **7. MARKETING AUTHORISATION HOLDER** INTERVET, RUE OLIVIER DE SERRES, ANGERS TECHNOPOLE, 49071 BEAUCOUZE. **8. MARKETING AUTHORISATION NUMBER(S)** FR/V/0067423 0/1996 Paracox-8 Box of 1 sachet of 500 doses and 1 metal cannula with a Luer cone, Box of 1 sachet of 1000 doses and 1 metal cannula with a Luer cone, Box of 1 sachet of 4400 doses and 1 metal cannula with a Luer cone, Box of 1 sachet of 5000 doses and 1 metal cannula with a Luer cone. Solvent for spray-on-chickens 100 ml solvent, 500 ml solvent. **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION** 22/01/1996 – 23/09/2010 **10. DATE OF REVISION OF THE TEXT** 04/09/2017

GL/PAR/1217/0005

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