

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**4 ml & 20 ml vials**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paracox-8, suspension for oral suspension for chickens

**2. STATEMENT OF ACTIVE SUBSTANCES**

Oocysts per dose of 0.004 ml:

<i>E. acervulina</i> HP	500
<i>E. brunetti</i> HP	100
<i>E. maxima</i> CP	200
<i>E. maxima</i> MFP	100
<i>E. mitis</i> HP	1,000
<i>E. necatrix</i> HP	500
<i>E. praecox</i> HP	100
<i>E. tenella</i> HP	500

**3. PHARMACEUTICAL FORM**

Suspension for oral suspension

**4. PACKAGE SIZE**

4 ml (1,000 doses)  
20 ml (5,000 doses)

**5. TARGET SPECIES**

Chickens

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Solvent should be used when sprayed on chickens.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP: {MM/YYYY}

Once broached/diluted use immediately.

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated.

Do not freeze.

Protect from light.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: Read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
MK7 7AJ

**16. MARKETING AUTHORISATION NUMBER**

Vm 01708/4572

**17. MANUFACTURER’S BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS 4 ml & 20 ml vials**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paracox-8, suspension for oral suspension



**2. QUANTITY OF THE ACTIVE SUBSTANCES**

Per dose of 0.004 ml:

<i>E. acervulina</i> HP	500
<i>E. brunetti</i> HP	100
<i>E. maxima</i> CP	200
<i>E. maxima</i> MFP	100
<i>E. mitis</i> HP	1,000
<i>E. necatrix</i> HP	500
<i>E. praecox</i> HP	100
<i>E. tenella</i> HP	500

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

4 ml (1,000 doses)  
20 ml (5,000 doses)

**4. ROUTE(S) OF ADMINISTRATION**

Oral use

**5. WITHDRAWAL PERIOD(s)**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP: {MM/YYYY}

Once broached/diluted use immediately.

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE**

**Solvent**

**1. NAME OF THE DILUENT**

Solvent for spray-on-chickens

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

100 ml

500 ml

**4. ROUTE(S) OF ADMINISTRATION**

Read package leaflet before use.

**4. STORAGE CONDITIONS**

Store between 2 – 25 °C.

**5. BATCH NUMBER**

Lot (number)

**6. EXPIRY DATE**

EXP: {Month/Year}

**7. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Paracox-8, suspension for oral suspension for chickens**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ, UK

Manufacturer responsible for batch release<sup>1</sup>:

Vaccine and solvent for spray-on-chickens  
MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
Buckinghamshire, MK7 7AJ, UK

Merck Sharp & Dohme Animal Health S.L.  
Poligono Industrial El Montalvo I  
C/Zeppelin 6, Parcela 38  
37008 Carbajosa de la Sagrada (Salamanca)  
Spain

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paracox-8, suspension for oral suspension for chickens

**3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENT(S)**

**Active substances:**

Paracox-8 is a suspension of oocysts derived from eight precocious lines of coccidia, presented as a live attenuated oral vaccine.

Each dose of 0.004 ml of vaccine contains the following numbers of live sporulated oocysts\*

<i>E. acervulina</i> HP	500 per dose
<i>E. brunetti</i> HP	100 per dose
<i>E. maxima</i> CP	200 per dose
<i>E. maxima</i> MFP	100 per dose
<i>E. mitis</i> HP	1,000 per dose
<i>E. necatrix</i> HP	500 per dose

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<sup>1</sup> The printed package leaflet will state the name and address of the manufacturer of the release of the concerned batch only.



<i>E. praecox</i> HP	100 per dose
<i>E. tenella</i> HP	500 per dose

\*According to the *in vitro* counting procedure of the manufacturer at the time of blending and at release.

Solvent for spray-on-chickens

Carminic acid (red colourant, E120)  
Xanthan gum (E415)

#### **4. INDICATION(S)**

Spray-on-feed or in drinking water

For the active immunization of healthy chickens to reduce infection and clinical signs of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mitis*, *E. necatrix*, *E. praecox*, and *E. tenella*.

Onset of immunity: begins to develop within 10 days post vaccination.

Onset of immunity: at least 36 weeks when birds are housed in conditions that permit oocyst recycling.

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 oocyst excretion for *E. acervulina*, *E. brunetti*, *E. maxima*, *E. necatrix*, *E. praecox* and *E. tenella*.
- to reduce loss in weight gain for *E. acervulina*, *E. brunetti*, *E. mitis*, *E. necatrix*, *E. praecox* and *E. tenella*.

Onset of immunity: 21 days post vaccination.

Duration of immunity: 10 weeks.

#### **5. CONTRAINDICATIONS**

None.

#### **6. ADVERSE REACTIONS**

Mild lesions e.g. *E. acervulina*, *E. necatrix* and *E. tenella* (lesion score of +1 or +2 using the numerical ranking system of Johnson and Reid (1970)) have commonly been discovered in birds 3-4 weeks after vaccination in laboratory studies. Lesions of this severity will not affect the performance of chickens. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)

- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Chickens.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

By spray on feed, by spray on chickens or in drinking water. A single dose of vaccine (0.004 ml undiluted vaccine) should be administered to chickens between day old and 9 days of age, inclusive. It is necessary to shake the container vigorously for 30 seconds before use to ensure homogeneous suspension of the oocysts.

## **9. ADVICE ON CORRECT ADMINISTRATION**

### *a) in drinking water*

The product may be administered in water via line drinkers from first placement of the chicks at 1 day of age, provided that a procedure is used that ensures consumption of the vaccinated water evenly by all chicks, avoiding settlement of oocysts. For example, the following methods have been shown to be successful: The vaccine should be diluted to a concentration of 1 dose per 2 ml in cold tap water. Care should be taken to empty the vial completely by rinsing it in the water used to dilute the vaccine, and the diluted vaccine should be well stirred immediately before use. Calculate the total volume of water in the drinker system to be used, the average number of birds per drinking line and therefore the number of drinker lines and volume of diluted vaccine required. For static drinker lines, it is recommended that birds should be thirsted for 1-2 hours prior to administration. Each line should be drained and primed under gravity with diluted vaccine immediately before allowing birds access to the nipples. An initial charge (about 1 litre) of an indicator (e.g. milk) can be used to show when the line has been filled to the end and can be closed without wasting vaccine. Turn on the mains water supply when all of the diluted vaccine has been consumed. For drinker lines temporarily connected up to a recirculating system, it is recommended that vaccine dilution be carried out in a temporary reservoir incorporated within the circulation system, ensuring that the contents remain well mixed at all times. In order to mix the oocysts evenly, the diluted vaccine should be allowed to recirculate through the drinker lines before the birds are allowed to drink. The above examples are intended as a guide to illustrate the principles that should be followed in adapting a particular pipeline drinker system. Due to the difficulties associated with getting very young birds to drink from nipple drinkers, particular care should be taken to ensure that chicks of 1-3 days old take sufficient water for vaccine uptake when vaccinated using this method. Alternatively, vaccination using supplementary drinkers between 5-9 days may be preferred.

Occasionally on farms using nipple lines, supplementary drinkers are provided for the first 4-5 days. These may be fount-type drinkers or small bell-type drinkers which are automatically fed from the nipple line. If each supplementary drinker of this type is fed individually from the line, then the method of vaccination is essentially similar to bell-type drinkers. If, however, these drinkers are fed in sequence from a single nipple, one may encounter problems of air-locks after this type of drinker has been disconnected in order to deprive the birds of water for the 1-2 hours before vaccination. In this case it may be more appropriate to make an initial dilution of vaccine in a suitable container, e.g. a watering can, and pour the diluted vaccine into each drinker, as for individual founts.

#### IMPORTANT

The vaccine should not be administered into the main header tank of the watering system. The dilution of vaccine would be too high and the oocysts would not remain in suspension.

#### b) *on feed*

A method of application should be chosen that ensures rapid, even coverage of the total surface area of the feed available to the chicks. The vaccine may be sprayed, using a coarse spray, diluted in water. The vaccine should be diluted to a concentration of 1 dose per 0.4 ml (1,000 doses of Paracox-8 added to 400 ml of water, 5,000 doses of Paracox-8 added to 2 litres of water). Care should be taken to empty the vial completely by rinsing it in the water used to dilute the vaccine and to ensure that the applicator reservoir is agitated regularly throughout application to avoid settling out of oocysts.

#### c) *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 5,000 doses diluted vaccine, a total of  $0.21 \times 5,000 = 1,050$  ml diluted vaccine is needed and is divided over the vaccine, solvent and water as below:

1. 20 ml Paracox-8 vaccine (1 vial)
2. 500 ml Solvent (1 bottle)
3. Fill up to 1,050 ml with tap water

I.e. for the preparation of 1,000 doses diluted vaccine, a total of  $0.21 \times 1,000 = 210$  ml diluted vaccine is needed and is divided over the vaccine, solvent and water as below:

1. 4 ml Paracox-8 vaccine (1 vial)
2. 100 ml Solvent (1 bottle)
3. Fill up to 210 ml with tap water

The solvent contains a red colouring agent and xanthan gum, both of which are included for better uptake. Water used for vaccine dilution should be fresh, cool and free of pollution.

Use clean containers for vaccine preparation. Shake the 5,000-dose (or 1,000-dose) vial of Paracox-8 vigorously for 30 seconds to ensure re-suspension of the oocysts.

Empty the content of the vial completely by rinsing with a small quantity of the water used to dilute the vaccine. Empty the content of the solvent bottle completely by rinsing with the remaining amount of water and mix to a uniform solution. Add the vaccine solution to the solvent solution 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-lighted area to allow time for the birds to preen.

#### **10. WITHDRAWAL PERIOD(S)**

Zero days.

#### **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

##### Paracox-8

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton.

Shelf-life after dilution according to directions: use immediately.

##### Solvent for spray-on-chickens

Store between 2 °C – 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

#### **12. SPECIAL WARNING(S)**

##### Special warnings for each target species:

Vaccinate healthy animals only.

##### Special precautions for use in animals

Food and water provided at any stage before or after vaccination must be free from anticoccidial agents including sulphonamides and antibacterial agents having anticoccidial activity.

The vaccine contains live coccidian oocysts and is dependent upon replication of the vaccinal lines within the host for development of protection. It is common to find oocysts in the gastrointestinal tract of vaccinated birds from 1-3 weeks or more after vaccination. These oocysts are most likely to be vaccinal oocysts which recycle in the birds/litter. This ensures satisfactory flock protection against all the pathogenic strains of the same species of *Eimeria* that are contained in the vaccine.

Chickens should be healthy and reared on floor with litter. Litter should be removed, and the chicken housing thoroughly cleaned and disinfected between rearing cycles, to minimize carry over to the next flock. This will reduce the chances of a coccidial field challenge occurring before the development of adequate flock protection.

Particular care should be taken to ensure that all chicks take water when vaccinated by pipeline nipples at day-old.

Do not administer to dry drinkers.

Ensure that all vaccination equipment is thoroughly cleaned before use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

For administration by spray-on-chickens the vaccine should be diluted with solvent for spray-on-chickens.

Wash hands immediately after use.

Personal protective equipment consisting of masks and eye protection should be worn when spraying the vaccine.

Lay:

Do not use in birds in lay.

Interaction with other medicinal products and other forms of interaction:

Since the protection against coccidial infection following vaccine administration is enhanced by natural challenge, it should be noted that access to any therapeutic agents having anticoccidial activity at any time following vaccination may reduce the duration of effective protection. This is particularly important in the four weeks following vaccination.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes)

Severe overdose ( $\times 5$  or more) may lead to a temporary reduction in daily live weight gain.

Incompatibilities:

Do not mix with any other veterinary medicinal product except the solvent recommended for use for spray administration.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL**

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

February 2022

**15. OTHER INFORMATION**

For animal treatment only.

In any animal population there may be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct 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.

Paracox-8 is an attenuated, live coccidiosis vaccine for oral administration to chickens.

Induces specific immunity to wild strains of *Eimeria* species contained in this vaccine, when ingested by chickens.

Pack sizes:

Paracox-8

Cardboard box with 1 vial of vaccine containing 4 ml (1,000 doses)

Cardboard box with 1 vial of vaccine containing 20 ml (5,000 doses)

Solvent for spray-on-chickens

For administration by spray-on-chickens, the vaccine is supplied together with the appropriate volume of solvent:

100 ml bottle of solvent (for 1,000 doses)

500 ml bottle of solvent (for 5,000 doses)

Not all pack sizes may be marketed.

Approved 18 February 2022

A handwritten signature in black ink, appearing to read "A. Hunter". The signature is stylized and written in a cursive-like font.