

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (ie. Outer cover of the label/leaflet that is attached to the outer box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paracox-5, suspension for oral suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 0.004 ml:

<i>Eimeria acervulina</i> HP	500 – 650 oocysts
<i>Eimeria maxima</i> CP	200 – 260 oocysts
<i>Eimeria maxima</i> MFP	100 – 130 oocysts
<i>Eimeria mitis</i> HP	1000 – 1300 oocysts
<i>Eimeria tenella</i> HP	500 – 650 oocysts

3. PHARMACEUTICAL FORM

Suspension for oral suspension

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Solvent can 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 01708/4552

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-5, suspension for oral suspension for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCES

Per dose of 0.004 ml:

<i>E. acervulina</i> HP	500 – 650	oocysts
<i>E. maxima</i> CP	200 – 260	oocysts
<i>E. maxima</i> MFP	100 – 130	oocysts
<i>E. mitis</i> HP	1000 – 1300	oocysts
<i>E. tenella</i> HP	500 – 650	oocysts

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.

ml & 500 ml bottles

1. NAME OF THE DILUENT

Solvent for spray-on-chickens

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

100 ml
500 ml

3. 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-5, 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

Manufacturer responsible for batch release:¹

Vaccine and solvent for spray-on-chickens

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Bucks, 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-5, suspension for oral suspension for chickens

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each 0.004 ml dose of vaccine contains the following numbers of sporulated oocysts derived from precocious lines of coccidia:

Active substances:

<i>Eimeria acervulina</i> HP	500 – 650 oocysts*
<i>Eimeria maxima</i> CP	200 – 260 oocysts*
<i>Eimeria maxima</i> MFP	100 – 130 oocysts*

¹ The printed package leaflet will state the name and address of the manufacturer responsible for

the release of the concerned batch only.

<i>Eimeria mitis</i> HP	1000 – 1300 oocysts*
<i>Eimeria tenella</i> HP	500 – 650 oocysts*

*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, spray-on-chicken without solvent or in drinking water

For the active immunisation of chickens to reduce infection and clinical signs of coccidiosis caused by *Eimeria acervulina*, *E. maxima*, *E. mitis* and *E. tenella*.

Onset of immunity: begins to develop within 14 days post vaccination.

Duration of immunity: at least 40 days post vaccination.

Spray-on-chickens with solvent

For the active immunisation of chickens against coccidiosis caused by *Eimeria acervulina*, *E. maxima*, *E. mitis* and *E. tenella*:

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

Onset of immunity: 21 days post vaccination.

Duration of immunity: 10 weeks.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Mild lesions of e.g. *E. Acervulina* and *E. tenella* (lesion scores of +1 or +2 using the numerical ranking system of Johnson and Reid, 1970) have commonly been discovered in birds 3 to 4 weeks after vaccination in laboratory studies. Lesions of this severity will not affect the performance of immune chickens.

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

Dosage

A single dose of vaccine is administered to chickens from one day of age via spray on feed, via spray on chickens, or at 3 days old via drinking water. The nominal dose is 0.004 ml per chicken. Each 4 ml container will provide sufficient vaccine for 1,000 chickens and each 20 ml container will provide sufficient vaccine for 5,000 chickens.

Administration

Chickens should be floor reared on litter.

On feed

Sufficient starter feed for the first 24-48h should be laid out on paper or plastic along the floor of the poultry house. Shake the container vigorously for 30 seconds before use, to ensure re-suspension of the oocysts. Dilute Paracox-5 in water at the rate of approximately 5000 doses in up to 3 litres of water and spray evenly over the surface of the feed using a coarse spray. Ensure a controlled, even coverage of the total surface area of the feed available to the chicks. Agitate the applicator reservoir regularly throughout application to avoid settling out of oocysts. Once the vaccine has been diluted for use it should be sprayed onto feed and birds should be placed with access to feed within two hours. When the treated allocation of feed has been consumed, routine feeding may continue.

In drinking water

Place chicks in the house at day-old and encourage them to become accustomed to the nipple drinker system. When the chicks are 3 days old the lighting system is turned off for about 7 hours. Raise all drinking lines out of reach of the chicks for about two hours before administration of the vaccine. At the same time the lighting is switched on. Drain each drinking line completely. Dilute the vaccine to a concentration of 1 dose/2 - 4ml in cold tap water.

Calculate the average number of birds per drinking line and calculate the volume of diluted vaccine needed per drinking line at a rate 2 - 4 ml per bird.

Fill each line with diluted vaccine and lower to allow the 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. As the birds drink, keep each line full via its reservoir until all the diluted vaccine prepared for that line has been added. Normal water supply then follows.

By spray-on-chickens

For administration by spray on chickens, red food colouring agent Cochineal E120 should be added to the diluted vaccine, or the vaccine should be diluted using the recommended solvent "Solvent for spray-on chickens" The solvent contains red colouring agent and xanthan gum, both of which are included for better uptake.

a) Solvent for spray-on-chickens

Vaccine should be delivered using a dose volume of between 0.21 and 0.28 ml 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 $0.21 \times 5000 = 1050$ ml diluted vaccine is needed and is divided over the vaccine, solvent and water as below:

1. 20 ml Paracox-5 vaccine (1 vial)
2. 500 ml Solvent (1 bottle)
3. Fill up to 1050 ml with tap water

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 to the container and mix solvent and water to a uniform solution. Shake the 5000 dose (or 1000 dose) vial of Paracox-5 vigorously for 30 seconds to ensure re-suspension of the oocysts. Add the entire contents of the vial 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-lighted area to allow time for the birds to preen.

b) Red food colouring agent (E120).

Vaccine should be delivered using a dose volume of between 0.21 and 0.28 ml diluted vaccine per bird using 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) and add this volume of water to a suitable container (normally between 1.0 and 1.5 litres for 5,000 doses or 200 and 300 ml for 1,000 doses). Uptake of the vaccine by the birds, and therefore the efficacy of the

vaccine, is improved if a red food colouring agent is added to the diluted vaccine before administration by spray. Add sufficient red food colouring agent (cochineal E120) to the water to give a concentration of 0.1% w/v.

Shake one 5,000 dose (or 1,000 dose) vial of Paracox-5 vigorously for 30 seconds to ensure resuspension of the oocysts. Add the entire contents of the vial to the diluent and mix thoroughly. Add the diluted vaccine to the applicator reservoir and operate the cabinet to 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 chicks. Agitate the applicator reservoir regularly throughout application to avoid settling out of oocysts. Leave the birds in the box for at least 30 minutes in a well-lit area to allow time for the birds to preen.

9. ADVICE ON CORRECT ADMINISTRATION

On feed

Ensure that all available feed is treated and that the total number of doses dispensed matches the number of birds in the house. Do not administer the vaccine via an automatic feeding machine or place treated feed directly under heating lamps.

In drinking water

It is recommended that before using the vaccine in a facility for the first time, precautions are taken to check that the procedure ensures the drinking lines have been properly primed with Paracox-5, as shown by the appearance of the indicator from nipples at the end the line, before the chicks are allowed to start drinking.

By spray-on-chickens

For administration by spray on chickens a red food colouring agent should be added to the diluted vaccine or the vaccine should be diluted using "Solvent for spray-on chickens", supplied by the manufacturer. For the spray-on-chicken method of administration a significant reduction in efficacy may be observed if diluted in tap water only. The purity of Cochineal E120 should be in compliance with Commission Directive 95/45/EC.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Paracox-5

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

Do not freeze.

Protect from light.

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 (EXP), which is stated on the label/carton.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only. Do not administer to stressed chicks, e.g. chilled, not feeding or drinking.

For administration by spray-on-chickens a red food colouring agent should be added to the diluted vaccine, or the vaccine should be diluted using “Solvent for spray-on-chickens”. For the spray-on-chicken method of administration a significant reduction in efficacy may be observed if diluted in tap water only.

Chickens should be strictly floor reared on litter. 'Paracox-5' vaccine contains live coccidia 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 via the litter. Recycling ensures satisfactory flock protection against all the pathogenic species of *Eimeria* contained in the vaccine.

Measures should be taken to ensure that the bulk diluted vaccine is resuspended at intervals during administration.

Since the protection against coccidial infection following “Paracox-5” administration is enhanced by natural challenge, it should be noted that access to any therapeutic agents having anti-coccidial activity at any time following vaccination may reduce the duration of effective protection. This is important throughout the life of the chicken.

To reduce the chance of coccidial field challenge before the onset of immunity,

litter should be removed and chicken housing should be thoroughly cleaned between rearing cycles.

Special precautions for use in animals:

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:

Personal protective equipment consisting of well-fitting 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 interactions:

Do not administer anticoccidial agents including sulphonamides and antibacterial agents before or after vaccination with Paracox-5.

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 other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):

Severe overdose (x 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 MATERIALS, IF ANY

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

October 2020

15. OTHER INFORMATION

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, nutritional status, concurrent drug therapy and stress.

Pack sizes:

Paracox-5

4 ml container (1000 dose) x 5

20 ml container (5000 dose) x 5

Solvent for spray-on-chickens

100 ml container for 1000 doses

500 ml container for 5000 doses

The appropriate volume of solvent is supplied together with the vaccine (100 ml solvent for 1000 doses, 500 ml for 5000 doses).

Not all pack sizes may be marketed.