# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paracox-5 suspension for oral suspension for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.004 ml dose of vaccine contains:

**Active substances:**

Sporulated oocysts derived from five precocious lines of coccidia:

| | |
|---|---|
| *Eimeria acervulina,* strain HP, live | 500 – 650 oocysts* |
| *Eimeria maxima,* strain CP, live | 200 – 260 oocysts* |
| *Eimeria maxima,* strain MFP, live | 100 – 130 oocysts* |
| *Eimeria mitis,* strain HP, live | 1000 – 1300 oocysts* |
| *Eimeria tenella,* strain HP, live | 500 – 650 oocysts* |

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

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| ***Suspension***: |
| Phosphate buffered saline |
| ***Solvent for spray-on-chickens***: |
| Carminic acid (Red colourant, E120) |
| Xanthan gum (E415) |
| Sodium chloride |
| Water for injections |

Suspension: milky suspension after mixing.
Solvent for spray-on-chickens [Solvent for Paracox for spray-on-chickens administration (BE)]: semi-opaque, red, viscous solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Chickens.

### 3.2 Indications for use for each target species

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: 14 days after vaccination.
Duration of immunity: 40 days after 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 after vaccination.
Duration of immunity: 10 weeks after vaccination.

### 3.3 Contraindications

None.

### 3.4 Special warnings

Vaccinate healthy animals only.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not administer to stressed chicks, e.g. chilled, not feeding or drinking.
For administration by spray on chickens, a red food colouring agent (Cochineal E120) should be added to the diluted vaccine, or the vaccine should be diluted using the recommended "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 without red colourant. The purity of the cochineal E120 must be in compliance with Commission Directive 95/45/EC.
Chickens should be strictly floor reared on litter. The 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 the vaccine 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.
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.

Other precautions:
Not applicable

### 3.6 Adverse events

Chickens:

| | |
|---|---|
| Common | Intestinal lesion.[1]. |

| | |
|---|---|
| (1 to 10 animals / 100 animals treated): | |

[1] Mild intestinal 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. Lesions of this severity will not affect the performance of immune chickens.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.{< > to be adjusted nationally}

### 3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay.

### 3.8 Interaction with other medicinal products and other forms of interaction

Do not administer anticoccidial agents including sulphonamides and antibacterial agents before or after vaccination with the veterinary medicinal product.
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.

### 3.9 Administration routes and dosage

A single dose of the vaccine should be administered to chickens from one day of age by spray-on-feed, by spray-on-chickens, or at 3 days old via drinking water.

*Administration via feed*
Sufficient starter feed for the first 24 - 48 hours should be laid out on paper or plastic along the floor of the poultry house. Do not administer the vaccine via an automatic feeding machine or place treated feed directly under heating lamps.
Shake the container vigorously for 30 seconds before use, to ensure re-suspension of the oocysts.
Dilute the vaccine 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. Ensure that all available feed is treated and that the total number of doses dispensed matches the number of birds in the house.
Once the vaccine has been diluted for use it should be sprayed onto feed and birds should be placed with access to the feed within two hours.
When the treated allocation of feed has been consumed, routine feeding may continue.

*Administration via 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 - 4 ml 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.

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 the vaccine, as shown by the appearance of the indicator from nipples at the end the line, before the chicks are allowed to start drinking.

*Administration via 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 5000 doses (or by 10 for 1000 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. 20 ml 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 the vaccine 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 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 5000 doses (or by 10 for 1000 doses) and add this volume of water to a suitable container (normally between 1.0 and 1.5 litres for 5000 doses or 200 and 300 ml for 1000 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, equivalent to 210-280 µg/bird. Shake one 5000 dose (or 1000 dose) vial of the vaccine vigorously for 30 seconds to ensure resuspension of the oocysts. Add the entire contents of the vial to the solvent 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-lighted area to allow time for the birds to preen.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Severe overdose (5 fold or more) may lead to a temporary reduction in daily live-weight gain.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Zero days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 ATCvet code: QI01AN01.

Induces specific immunity to wild strains of these *Eimeria* species when ingested by chickens.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

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

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 33 weeks.
Shelf life of solvent as packaged for sale: 2 years.
Shelf life after dilution according to directions: use immediately.

### 5.3 Special precautions for storage

Vaccine
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent
Store between 2 °C – 25 °C.

### 5.4 Nature and composition of immediate packaging

Vaccine
Clear, colourless PETG (polyethylene terephthalate copolyester) vial, closed with bromobutyl stopper and sealed with an aluminium cap.

Pack sizes:
Box with 5 vials containing 4 ml (1000 doses)
Box with 5 vials containing 20 ml (5000 doses)

Solvent
PET bottles closed with a rubber stopper and sealed with an aluminium cap.
For administration by spray-on-chickens, “Solvent for spray-on-chickens” can be used to dilute the vaccine. 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.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater <or household waste >.
{< > to be adjusted nationally}

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

{to be completed nationally}

## 7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 28/06/1999.

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}
{to be completed nationally}

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box with 5 vials containing 4 ml & Box with 5 vials containing 20 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paracox-5 suspension for oral suspension

## 2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 0.004 ml:

| | |
|---|---|
| *Eimeria acervulina* HP | 500 – 650 oocysts |
| *Eimeria maxima* CP | 200 – 260 oocysts |
| *Eimeria maxima* MFP | 100 – 130 oocysts |
| *Eimeria mitis* HP | 1000 – 1300 oocysts |
| *Eimeria tenella* HP | 500 – 650 oocysts |

## 3. PACKAGE SIZE

5 x 4 ml (1000 doses)
5 x 20 ml (5000 doses)

## 4. TARGET SPECIES

Chickens

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral use.
Solvent can be used when sprayed on chickens.

## 7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached/diluted use immediately.

## 9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.
Protect from light.

## 10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

## 11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

{to be completed nationally.}

## 14. MARKETING AUTHORISATION NUMBERS

{to be completed nationally.}

## 15. BATCH NUMBER

Lot {number}

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

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paracox-5

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Per dose of 0.004 ml:

| | |
|---|---|
| *E. acervulina* HP | 500 – 650 oocysts |
| *E. maxima* CP | 200 – 260 oocysts |
| *E. maxima* MFP | 100 – 130 oocysts |
| *E. mitis* HP | 1000 – 1300 oocysts |
| *E. tenella* HP | 500 – 650 oocysts |

4 ml (1000 doses)
20 ml (5000 doses)

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached/diluted use immediately.

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT**
**Label Bottles 100 ml & 500 ml**

## 1. NAME OF THE SOLVENT

Solvent for spray-on-chickens
[Solvent for Paracox for spray-on-chickens administration (BE)]

Bottle of 100 ml
Bottle of 500 ml

## 2. TARGET SPECIES

Chickens.

## 3. ROUTE(S) OF ADMINISTRATION

Read the Paracox-5/-8 package leaflet before use.

## 4. EXPIRY DATE

Exp. {mm/yyyy}

## 5. SPECIAL STORAGE PRECAUTIONS

Store between 2 – 25 °C.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

## 7. BATCH NUMBER

Lot {number}

**PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Paracox-5 suspension for oral suspension for chickens

## 2. Composition

Each 0.004 ml dose of vaccine contains:

**Active substances:**
Sporulated oocysts derived from precocious lines of coccidia:

| | |
|---|---|
| *Eimeria acervulina,* strain HP, live | 500 – 650 oocysts* |
| *Eimeria maxima,* strain CP, live | 200 – 260 oocysts* |
| *Eimeria maxima,* strain MFP, live | 100 – 130 oocysts* |
| *Eimeria mitis,* strain HP, live | 1000 – 1300 oocysts* |
| *Eimeria tenella,* strain HP, live | 500 – 650 oocysts* |

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

Suspension: milky suspension after mixing.
Solvent for spray-on-chickens [Solvent for Paracox for spray-on-chickens administration (BE)]: semi-opaque, red, viscous solution.

## 3. Target species

Chickens.

## 4. Indications for use

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: 14 days after vaccination.
Duration of immunity: 40 days after 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 after vaccination.
Duration of immunity: 10 weeks after vaccination.

## 5. Contraindications

None.

## 6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
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. The 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 the vaccine 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.
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.

Laying birds:
Do not use in birds in lay.

Interaction with other medicinal products and other forms of interaction:
Do not administer anticoccidial agents including sulphonamides and antibacterial agents before or after vaccination with the veterinary medicinal product.
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:
Severe overdose (x 5 or more) may lead to a temporary reduction in daily live-weight gain.

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

## 7. Adverse events

Chickens:

| | |
|---|---|
| Common | Intestinal lesion.[1]. |

| | |
|---|---|
| (1 to 10 animals / 100 animals treated): | |

[1] Mild intestinal 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. Lesions of this severity will not affect the performance of immune chickens.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

## 8. Dosage for each species, routes 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 1000 chickens and each 20 ml container will provide sufficient vaccine for 5000 chickens.

**Administration**
Chickens should be floor reared on litter.

*On feed*
Sufficient starter feed for the first 24-48 hours 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 the vaccine 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 – 4 ml 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 5000 doses (or by 10 for 1000 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. 20 ml 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 the vaccine 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 5000 doses (or by 10 for 1000 doses) and add this volume of water to a suitable container (normally between 1.0 and 1.5 litres for 5000 doses or 200 and 300 ml for 1000 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 5000 dose (or 1000 dose) vial of the vaccine vigorously for 30 seconds to ensure resuspension of the oocysts. Add the entire contents of the vial to the solvent 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 the vaccine, 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 periods

Zero days.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Vaccine
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 which is stated on the label/box after Exp. The expiry date refers to the last day of that month.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.
{< > to be adjusted nationally}

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

{to be completed nationally}

Pack sizes:
Vaccine
Box with 5 vials containing 4 ml (1000 doses)
Box with 5 vials containing 20 ml(5000 doses)

Solvent
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.

## 15. Date on which the package leaflet was last revised

{MM/YYYY} {to be completed nationally}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}
<Manufacturer responsible for batch release:[1]> {to be adjusted nationally if included in the above}
MSD Animal Health UK Limited
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

[[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.]

<Local representative and contact details to report suspected adverse reactions>:>
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

## 17. 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. {to be completed nationally}