

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac *E. coli* lyophilisate for suspension for spray vaccination for chickens and turkeys or for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

Active substance:

Live *aroA* gene deleted *Escherichia coli*, 5.2 x 10⁶ - 9.1 x 10⁸ CFU*
type O78, strain EC34195

* Colony forming units when grown on trypticase soy agar plates.

Excipients:

Qualitative composition of excipients and other constituents
Sucrose
Ammonium sulphate
Magnesium sulphate heptahydrate
Potassium phosphate monobasic
Sodium phosphate dibasic heptahydrate

Cream coloured lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers, future layers/breeders) and turkeys.

3.2 Indications for use for each target species

For active immunisation of broiler chickens, future layer/breeders and turkeys in order to reduce mortality and lesions (pericarditis, perihepatitis, airsacculitis) associated with *Escherichia coli* serotype O78.

Onset of immunity:

Chickens: 2 weeks after vaccination for the reduction of lesions. The onset of immunity has not been established for the mortality claim.

Turkeys: 3 weeks after second vaccination for the reduction of lesions and mortality.

Duration of immunity:

Chickens: 8 weeks for the reduction of lesions and 12 weeks for the reduction of mortality (spray). 12 weeks for the reduction of lesions and mortality (drinking water).

Turkeys: duration of immunity has not been established.

A cross protection study showed reduction of incidence and severity of airsacculitis caused by *E. coli* serotypes O1, O2 and O18 for spray application for chickens. For these serotypes no onset of immunity or duration of immunity was established.

3.3 Contraindications

Do not vaccinate animals undergoing antibacterial or immunosuppressive treatment.

3.4 Special warnings

Vaccinate healthy animals only.

Do not use antibiotic treatment within 1 week before and after vaccination because antibiotic treatment might impair the efficacy of the vaccine.

No information is available on the influence of high levels of maternally derived antibodies on the efficacy.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine strain can be detected in tissues (liver, heart) until 6 days (chickens) or in tissues (thoracic air sacs) 4 days (turkeys) post vaccination. Vaccinated birds may excrete the vaccine strain by faecal route for up to 5 weeks (chickens) or 7 days (turkeys) post vaccination and the vaccine may remain present in the environment until the end of the finishing or rearing period (chickens) or for 7 days (turkeys).

Therefore, it is recommended to clean and disinfect bird houses where the vaccine was applied after completion of the finishing or rearing period.

The vaccine strain may spread to in-contact birds. The vaccine strain can be identified by its growth properties on biological growth media: it shows normal growth on MacConkey and trypticase soy agar, while no colonies are observed when plated without aromatic amino acids (minimum agar).

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

Apply the usual aseptic precautions to all administration procedures.

The use of eye-protection, gloves and a nose-mouth mask by the operator is advised during administration. Immunosuppressed people should not be present during administration of the vaccine. Disinfect hands and equipment after use.

Personnel involved in attending vaccinated animals should follow general hygiene principals and take particular care in handling litter from recently vaccinated animals.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Immunisation has to be considered as one component in a complex control program that addresses all important hygienic and health factors for poultry.

3.6 Adverse events

Chickens (broilers, future layers/breeders) and turkeys:

None known.

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 section 'Contact details' of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has been demonstrated when administered to chickens during lay at one dose by both coarse spray and drinking water administration. However, the efficacy of the veterinary medicinal product has not been demonstrated when administered to chickens during lay. A decision to use this vaccine in chickens during lay should be made on a case by case basis.

The safety of the veterinary medicinal product has not been investigated in turkeys during lay. Do not use in turkeys in lay and within 6 weeks before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

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

Coarse spray administration for chickens and turkeys or for use in drinking water for chickens.

Vaccination schedule

Chickens: One dose of vaccine from 1 day of age by coarse spray administration or one dose of vaccine from 5 days of age by drinking water administration.

Turkeys: One dose of vaccine from 1 day of age followed by second dose of vaccine 3 weeks later by coarse spray administration.

Administration

Spray application:

Use clean vaccination materials and turn off ventilation until 15 minutes after vaccination.

Remove seal and stopper. Half-fill the vial with chlorine-free water at room temperature. Replace the stopper and shake well until dissolved. Pour the reconstituted vaccine into a clean container and add chlorine-free water to further dilute the vaccine in order to obtain an even distribution when sprayed onto the birds.

No disinfectants or other substances impairing the performance of the live vaccine should be used in the sprayer.

Dilute and administer the reconstituted vaccine at a rate of one dose of reconstituted vaccine per bird, according to the directions of your specific coarse spray vaccination equipment. The recommended volume for 1 dose is between 0.1 and 0.5 ml. The spraying distance should be between 30 and 80 cm above the animals in order to ensure an even distribution and the recommended droplet size is greater than 100 µm.

In drinking water use:

Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any trace of disinfectants, detergents, soap, etc. and antibiotics. Contact with disinfectants makes the vaccine ineffective.

Allow water to be consumed so that levels of drinkers are minimal before vaccine is applied. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water.

It may be necessary to withhold water prior to vaccination in order to ensure that all birds drink during the vaccination period.

Open the vaccine vial under water and dissolve thoroughly in a container. Care should be taken to empty the vial and its top completely by rinsing them in water. Do not split large vials to vaccinate more than 1 house or drinking system, as this may lead to mixing errors.

Use cold and fresh non-chlorinated water that is free from metal-ions. Low-fat skimmed milk powder (i.e. < 1% fat) may be added to the water (2–4 grams per litre) or skimmed milk (20–40 ml per litre of water) to improve the water quality and to increase the stability of the bacteria.

Ideally, vaccine should be administered in the volume of water consumed by the birds in up to 3 hours. The aim is to give every bird one dose of vaccine. As a general rule, apply reconstituted vaccine to chlorine-free and fresh water at the rate of 1,000 doses of the vaccine to 1 litre of water per day of age for 1,000 chickens, e.g. 10 litres would be needed for 1,000 10-day old chickens. If in doubt, measure water intake the day before administering vaccine.

Upon reconstitution, transparent to white-yellowish and opaque suspension (depending on the volume of diluent used).

Administer the dissolved vaccine to birds immediately after reconstitution.
Avoid exposure of the vaccine suspension to sunlight.

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

No adverse events have been observed after the administration of a 10-fold overdose of the vaccine.

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: QI01AE04

To stimulate active immunity to *Escherichia coli* serotype O78.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as package for sale: 30 months.
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Type I borosilicate glass vial of 10 ml for 2,500 and 5,000 dose-presentations and 50 ml for 10,000 and 20,000 dose-presentations with a chlorobutyl rubber stopper sealed with aluminium crimp caps.

Cardboard box of one vial of 2,500, 5,000, 10,000 or 20,000 doses.

Cardboard box of ten vials of 2,500, 5,000, 10,000 or 20,000 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.

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

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/12/140/001-008

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 15/06/2012.

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

{DD/MM/YYYY}

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>).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of one vial of 2,500 or 5,000 or 10,000 or 20,000 doses
Cardboard box of ten vials of 2,500 or 5,000 or 10,000 or 20,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac E. coli lyophilisate for suspension for spray vaccination for chickens and turkeys or for use in drinking water for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Live aroA gene deleted *Escherichia coli*, type O78, 5.2 x 10⁶ - 9.1 x 10⁸ CFU/dose

3. PACKAGE SIZE

1 x 2,500 doses, 10 x 2,500 doses
1 x 5,000 doses, 10 x 5,000 doses
1 x 10,000 doses, 10 x 10,000 doses
1 x 20,000 doses, 10 x 20,000 doses

4. TARGET SPECIES

Chickens (broilers, future layers/breeders) and turkeys.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spray vaccination for chickens and turkeys or for use in drinking water for chickens.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/12/140/001 2500 ds 1 vial
EU/2/12/140/002 2500 ds 10 vials
EU/2/12/140/003 5000 ds 1 vial
EU/2/12/140/004 5000 ds 10 vials
EU/2/12/140/005 10000 ds 1 vial
EU/2/12/140/006 10000 ds 10 vials
EU/2/12/140/007 20000 ds 1 vial
EU/2/12/140/008 20000 ds 10 vials

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL

2,500, 5,000, 10,000, 20,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac E. coli



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Live *E. coli*: 5.2×10^6 - 9.1×10^8 CFU/dose

2,500 doses

5,000 doses

10,000 doses

20,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Poulvac E. coli lyophilisate for suspension for spray vaccination for chickens and turkeys or for use in drinking water for chickens

2. Composition

One dose contains:

Active substance:

Live aroA gene deleted *Escherichia coli*, 5.2 x 10⁶ - 9.1 x 10⁸ CFU*
type O78, strain EC34195

* Colony forming units when grown on trypticase soy agar plates.

Cream coloured lyophilisate.

3. Target species

Chickens (broilers, future layers/breeders) and turkeys.

4. Indications for use

For active immunisation of broiler chickens, future layer/breeders and turkeys in order to reduce mortality and lesions (pericarditis, perihepatitis, airsacculitis) associated with *Escherichia coli* serotype O78.

Onset of immunity:

Chickens: 2 weeks after vaccination for the reduction of lesions. The onset of immunity has not been established for the mortality claim.

Turkeys: 3 weeks after second vaccination for the reduction of lesions and mortality.

Duration of immunity:

Chickens: 8 weeks for the reduction of lesions and 12 weeks for the reduction of mortality (spray).

12 weeks for the reduction of lesions and mortality (drinking water).

Turkeys: duration of immunity has not been established.

A cross protection study showed reduction of incidence and severity of airsacculitis caused by *E. coli* serotypes O1, O2 and O18 for spray application for chickens. For these serotypes no onset of immunity or duration of immunity was established.

5. Contraindications

Do not vaccinate animals undergoing antibacterial or immunosuppressive treatment.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Do not use antibiotic treatment within 1 week before and after vaccination because antibiotic treatment might impair the efficacy of the vaccine.

No information is available on the influence of high levels of maternally derived antibodies on the efficacy.

Special precautions for safe use in the target species:

The vaccine strain can be detected in tissues (liver, heart) until 6 days (chickens) or in tissues (thoracic air sacs) 4 days (turkeys) post vaccination. Vaccinated birds may excrete the vaccine strain by faecal route for up to 5 weeks (chickens) or 7 days (turkeys) post vaccination and the vaccine may remain present in the environment until the end of the finishing or rearing period (chickens) or for 7 days (turkeys). Therefore, it is recommended to clean and disinfect bird houses where the vaccine was applied after completion of the finishing or rearing period.

The vaccine strain may spread to in-contact birds. The vaccine strain can be identified by its growth properties on biological growth media: it shows normal growth on MacConkey and trypticase soy agar, while no colonies are observed when plated without aromatic amino acids (minimum agar).

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

Apply the usual aseptic precautions to all administration procedures.

The use of eye-protection, gloves and a nose-mouth mask by the operator is advised during administration. Immunosuppressed people should not be present during administration of the vaccine. Disinfect hands and equipment after use.

Personnel involved in attending vaccinated animals should follow general hygiene principals and take particular care in handling litter from recently vaccinated animals.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Immunisation has to be considered as one component in a complex control program that addresses all important hygienic and health factors for poultry.

Laying birds:

The safety of the veterinary medicinal product has been demonstrated when administered to chickens during lay at one dose by both coarse spray and drinking water administration. However, the efficacy of the veterinary medicinal product has not been demonstrated when administered to chickens during lay. A decision to use this vaccine in chickens during lay should be made on a case by case basis.

The safety of the veterinary medicinal product has not been investigated in turkeys during lay. Do not use in turkeys in lay and within 6 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:

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:

No adverse events have been observed after the administration of a 10-fold overdose of the vaccine.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens (broilers, future layers/breeders) and turkeys:

None known.

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}.

8. Dosage for each species, routes and method of administration

Chickens: One dose of vaccine from 1 day of age by coarse spray or from 5 days of age by drinking water administration.

Turkeys: One dose of vaccine from 1 day of age followed by a second dose of vaccine 3 weeks later by coarse spray administration.

9. Advice on correct administration

Coarse spray administration for chickens and turkeys or for use in drinking water for chickens.

Spray application:

Use clean vaccination materials and turn off ventilation until 15 minutes after vaccination.

Remove seal and stopper. Half-fill the vial with chlorine-free water at room temperature. Replace the stopper and shake well until dissolved. Pour the reconstituted vaccine into a clean container and add chlorine-free water to further dilute the vaccine in order to obtain an even distribution when sprayed onto the birds.

No disinfectants or other substances impairing the performance of the live vaccine should be used in the sprayer.

Dilute and administer the reconstituted vaccine at a rate of one dose of reconstituted vaccine per bird, according to the directions of your specific coarse spray vaccination equipment. The recommended volume for 1 dose is between 0.1 and 0.5 ml. The spraying distance should be between 30 and 80 cm above the animals in order to ensure an even distribution and the recommended droplet size is greater than 100 µm.

In drinking water use:

Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any trace of disinfectants, detergents, soap, etc. and antibiotics. Contact with disinfectants makes the vaccine ineffective.

Allow water to be consumed so that levels of drinkers are minimal before vaccine is applied. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water.

It may be necessary to withhold water prior to vaccination in order to ensure that all birds drink during the vaccination period.

Open the vaccine vial under water and dissolve thoroughly in a container. Care should be taken to empty the vial and its top completely by rinsing them in water. Do not split large vials to vaccinate more than 1 house or drinking system, as this may lead to mixing errors.

Use cold and fresh non-chlorinated water that is free from metal-ions. Low-fat skimmed milk powder (i.e. < 1% fat) may be added to the water (2-4 grams per litre) or skimmed milk (20-40 ml per litre of water) to improve the water quality and to increase the stability of the bacteria.

Ideally, vaccine should be administered in the volume of water consumed by the birds in up to 3 hours. The aim is to give every bird one dose of vaccine. As a general rule, apply reconstituted vaccine to chlorine-free and fresh water at the rate of 1,000 doses of the vaccine to 1 litre of water per day of age for 1,000 chickens, e.g. 10 litres would be needed for 1,000 10-day old chickens. If in doubt, measure the water intake the day before administering vaccine.

Upon reconstitution, transparent to white-yellowish and opaque suspension (depending on the volume of diluent used).

Administer the dissolved vaccine to birds immediately after reconstitution.
Avoid exposure of the vaccine suspension to sunlight.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

EU/2/12/140/001-008

The vaccine is supplied in type I borosilicate glass vial of 10 ml or 50 ml with a chlorobutyl rubber stopper sealed with aluminium crimp caps.

Cardboard box of one vial of 2,500, 5,000, 10,000 or 20,000 doses.

Cardboard box of ten vials of 2,500, 5,000, 10,000 or 20,000 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Manufacturer responsible for batch release:

Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall de Bianya
17813 Girona
Spain

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien

Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
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Lietuva

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Luxembourg/Luxemburg

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Česká republika

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MT
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AT-1210 Wien
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Polska

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PT-2740-271 Porto Salvo
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Zoetis România S.R.L.
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Clădirea 2, Etaj 1-3, Sector 1,
București, 012095 - RO
Tel: +40785019479

Ireland

Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10,
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Loughlinstown,
Co. Dublin,
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Slovenská republika

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Sverige

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United Kingdom (Northern Ireland)

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2nd Floor, Building 10,
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17. Other information

To stimulate active immunity to *Escherichia coli* serotype O78.