PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box of 20 ml (10 doses), 100 ml (50 doses), 100 ml (100 doses), and 12 x 100 ml (12 x 100 doses) vials. 10/50/100 dose units: lyophilisates + solvents in one single cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enterisol Ileitis lyophilisate and solvent for oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Lawsonia intracellularis, strain MS B3903, live attenuated: $10^{4.9}$-$10^{6.1}$ $TCID_{50}$

3. PACKAGE SIZE

20 ml (10 doses) + 20 ml (solvent)
100 ml (50 doses) + 100 ml (solvent)
100 ml (100 doses) + 200 ml (solvent)
12 x 100 ml (12 x 100 doses) + 12 x 200 ml (solvent)

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted, use within 4 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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

UK(GB): Vm 61700/5000
UK(NI): Vm 61700/3000

15. BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {50 doses (100 ml) and 100 doses (100 ml) lyophilisate glass vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enterisol Ileitis lyophilisate for oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Lawsonia intracellularis, strain MS B3903, live attenuated: $10^{4.9}$-$10^{6.1}$ $TCID_{50}$

100 ml (50 doses)
100 ml (100 doses)

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted, use within 4 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

9. BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {20 ml (10 doses) lyophilisate glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enterisol Ileitis

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L. intracellularis (MS B3903) live attenuated

20 ml (10 doses)

3. BATCH NUMBER

Lot: {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted, use within 4 hours.

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL OF THE SOLVENT
(20 ml, 100 ml, 200 ml solvent)

1. NAME OF THE SOLVENT

Solvent for Enterisol Ileitis for pigs

2. TARGET SPECIES

Pigs

20 ml
100 ml
200 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. EXPIRY DATE

Exp. {mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

7. BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Enterisol Ileitis lyophilisate and solvent for oral suspension for pigs

2. Composition

Each 2 ml dose contains:

Active substances: *Lawsonia intracellularis,* strain MS B3903, live attenuated: $10^{4.9}$ - $10^{6.1}$ $TCID_{50}$*
* Tissue Culture Infective Dose 50%

Lyophilisate: light yellow to gold.
Solvent: clear, colourless solution.

3. Target species

Pigs

4. Indications for use

For active immunisation of weaned pigs from 3 weeks of age and older to reduce the intestinal lesions caused by *Lawsonia intracellularis* infection and to reduce growth variability and loss of weight gain associated with the disease.

Under field conditions, the difference in average daily weight gain was seen to be up to 30 g/day when vaccinated pigs were compared to unvaccinated pigs.

Onset of immunity:as early as 3 weeks post vaccination
Duration of immunity:for at least 17 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Do not vaccinate animals, which are receiving treatment with antimicrobials effective against *Lawsonia* spp. (see section “Interaction with other medicinal products and other forms of interaction”).

Efficacy of revaccination is unknown.

Special precautions for safe use in the target species:
In case of anaphylactic reactions, appropriate symptomatic treatment including the administration of glucocorticoids, adrenaline, or antihistamines is recommended.

The vaccine has not been tested in breeding boars. Therefore, the vaccination of breeding boars is not recommended.

The vaccine is an attenuated live vaccine and the potential for spreading to non-vaccinated animals cannot be excluded. However, based on the studies conducted with sentinel pigs, the apparent frequency of spreading and associated risk is very low. *Lawsonia intracellularis* DNA could be detected up to 3 days post vaccination in faecal samples of more than half of vaccinated animals, therefore transmission to pen-mates cannot be excluded in this time period.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid accidental contact with the skin. In the event of accidental skin contact, wash with soap or antibacterial wash and rinse well.

Pregnancy:
No adverse reaction was observed after administration of the vaccine in pregnant sows.

Fertility:
No adverse reaction was observed after administration of the vaccine in breeding sows.

Interaction with other medicinal products and other forms of interaction:
Since the vaccine isolate is a live bacterium, simultaneous use of antimicrobials which are effective against *Lawsonia* spp. should be avoided for a minimum of 3 days before and after vaccination (see section “Special warnings”).

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 reactions have been observed following administration of a 10-fold overdose.

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

7. Adverse events

Pigs:
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 its local representative using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Oral use.

All materials used in administering the vaccine must be free of antimicrobials, detergent or disinfectant residues to prevent inactivation.

Reconstitution with solvent:
10 and 50 dose presentation: Reconstitute the vaccine by adding the full content of the accompanying solvent to the vaccine. Shake well and use immediately.

100 dose presentation: Reconstitute the vaccine by adding half of the content of the accompanying solvent to the vaccine. Shake well and transfer the suspension back into the solvent bottle, mix with the remaining solvent to complete to a total volume of 200 ml. Shake well and use immediately.

Vaccination by drench application:
Administer a single 2 ml dose orally to pigs (from 3 weeks of age), irrespective of body weight.

Vaccination via the drinking water:
The systems must be cleaned and intensively rinsed with untreated water to avoid any residues of antimicrobials, detergents or disinfectants.

The final solution containing the vaccine should be consumed within 4 hours after preparation. Calculate the number of vials required to vaccinate all the pigs according to the table below:

No. of pigs:	Vaccine vial:	Solvent vial:
10	10 dose (20 ml)	20 ml
50	50 dose (100 ml)	100 ml
100	100 dose (100 ml)	200 ml

Dilute the reconstituted vaccine in drinking water on the basis of pre-measured water intake during a 4 hour time period of the previous day at the time of planned vaccination.

Vaccination via liquid feed:
The feeding systems and mixing device must be cleaned to avoid residues of antimicrobials, detergents or disinfectants.

Calculate the required number of vaccine vials as indicated in the table above.

Determine the amount of feed the animals will consume during one feeding session in less than 4 hours. The amount of feed should be defined by the feed uptake of the previous day, at the same feeding session for which the vaccination is planned.

9. Advice on correct administration

Visual appearance after reconstitution: light orange to pink semi-transparent suspension.

Vaccination via the drinking water:
Pigs will generally drink 8 to 12 % of their body weight per day, depending on environmental temperatures. The actual amount of water consumed may vary considerably depending on several factors. It is essential for the efficacy of the product that pigs receive at least the recommended dose. Therefore, it is recommended to assess the actual water intake over the 4 hours period the day before vaccination at same time the vaccination is planned to occur.

In case of vaccination using a trough the total water uptake within 4 hours needs to be provided. In case of vaccination via proportioner the required volume of stock solution for a 4 hour vaccination needs to be measured.

It is recommended to add skimmed milk powder or sodium thiosulfate solution as a stabiliser into the drinking water prior to adding the vaccine. The final concentration of the skimmed milk powder should be 2.5 g/litre. The final concentration of sodium thiosulfate should be approximately 0.055 g/litre.

After measuring the calculated water amount, sodium thiosulphate or skimmed milk powder should be added to the water. Afterwards, the reconstituted vaccine is to be diluted either in the water / skimmed milk or in the water / thiosulphate mixture.

Ensure that the reconstituted vaccine is evenly distributed in the water. Once even distribution has been achieved, fill the trough or the proportioner.

Vaccination via liquid feed:
Prepare liquid feed freshly with drinking water. The use of feed with controlled fermentation or feed containing formaldehyde is not recommended for vaccination as vaccine stability for these feed types was not tested. Reconstitute the vaccine using the provided solvent. Add the reconstituted vaccine to the fully prepared liquid feed.

Alternatively, to facilitate homogenous mixing the reconstituted vaccine may be further diluted with fresh drinking water containing 2.5 g/litre skimmed milk powder or 0.055 g/litre sodium thiosulfate and then mixed with the liquid feed. Ensure that the reconstituted vaccine is evenly distributed into the feed.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze. Protect from light.

Shelf life after reconstitution according to directions: 4 hours.

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

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

UK(GB): Vm 61700/5000
UK(NI): Vm 61700/3000

Cardboard box of 1 lyophilisate vial of 20 ml (10 doses) and 1 solvent vial of 20 ml.
Cardboard box of 1 lyophilisate vial of 100 ml (50 doses) and 1 solvent vial of 100 ml.
Cardboard box of 1 lyophilisate vial of 100 ml (100 doses) and 1 solvent vial of 200 ml.
Cardboard box of 12 lyophilisate vials of 100 ml (100 doses) and 12 solvent vials of 200 ml.
Corresponding vials of lyophilisate and solvent are packed together in one cardboard box.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Local representative and contact details to report suspected adverse events:

United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Ltd
Bracknell RG12 8YS
United Kingdom
Tel: +44 1344 746957

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany
Tel: +353 1 291 3985

17. Other information

The vaccine is designed to stimulate the development of an active immune response to *Lawsonia intracellularis* in pigs.
Seroconversion following vaccination cannot usually be detected, and is not related to protection.
The vaccine modulates the composition of the microbiome. Published literature suggests that this can reduce the *Salmonella* spp. prevalence in the acute phase of the infection and the seroprevalence at slaughter in *Lawsonia intracellularis* and *Salmonella enterica* co-infected pigs.

POM-V

Gavin Hall

Approved: 19 August 2026