1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enterisol Ileitis lyophilisate and solvent for oral suspension for pigs
(AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK)

Enterisol Ileitis vet. lyophilisate and solvent for oral suspension for pigs
(DK, NO, SE, FI, IS)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Lyophilisate:
Active substance:
Live attenuated *Lawsonia intracellularis* (MS B3903): $10^{4.9}$ - $10^{6.1}$ $TCID_{50}$*
* Tissue Culture Infective Dose 50%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for oral suspension.

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

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

Do not vaccinate animals which are receiving treatment with antimicrobials effective against *Lawsonia spp.* Such antimicrobials should be withheld for a minimum of 3 days before and 3 days after the day of vaccination (see section 4.8).

Efficacy of revaccination is unknown.

4.5 Special precautions for use

Special precautions for use in animals.
In case of anaphylactic reactions, appropriate symptomatic treatment including the administration of glucocorticoids, adrenaline, or antihistamines is 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No adverse reaction was observed after administration of the vaccine in breeding and pregnant animals.

4.8 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 4.4).

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.

4.9 Amounts to be administered and administration route

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 presentations: Reconstitute the vaccine by adding the full contents of the accompanying solvent to the vaccine. Shake well and use immediately.

100 dose presentation: Reconstitute the vaccine by adding half of the contents 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.
Visual appearance after reconstitution: light orange to pink semi-transparent suspension.

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 have to 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.

Pigs will generally drink 8 to 12 % of their body weight per day, depending on environmental temperature. 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 hours vaccination needs to be measured.

It is recommended to add skimmed milk powder or sodium thiosulfate solution as a stabilizer 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 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:
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.

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 to obtain a larger volume. This must be done 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions have been observed following administration of 10 times the recommended dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, live bacterial vaccines for pigs, *Lawsonia*
ATCvet code: QI09AE04

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 *L. intracellularis* and *Salmonella enterica* co-infected pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Gelatine
Potassium hydroxide
L-glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the vaccine lyophilisate as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 4 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I amber glass vial of 20 ml (10 doses), 100 ml (50 doses), 100 ml (100 doses) closed with a bromobutyl stopper with lacquered aluminium seal.

Solvent:
High density polyethylene vial containing 20 ml, 100 ml and, 200 ml closed with a chlorobutyl stopper with lacquered aluminium seal.

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 package sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

To be completed nationally: UK, FR

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: *To be completed nationally.*
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.