LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

20 ml (10 doses), 100 ml (50 doses), 100 ml (100 doses), and 12 x 100 ml (12 x 100 doses):
lyophilisate + solvent in one outer package

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enterisol Ileitis lyophilisate and solvent for oral suspension for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml):
Live attenuated *Lawsonia intracellularis* (MS B3903): $10^{4.9}$-$10^{6.1}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for oral suspension.

4. 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)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL 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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4294

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml (50 doses) and 100 ml (100 doses) lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enterisol Ileitis lyophilisate for oral suspension for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml):
Live attenuated *Lawsonia intracellularis* (MS B3903): $10^{4.9}$-$10^{6.1}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate for oral suspension

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4294

17. MANUFACTURER'S BATCH NUMBER

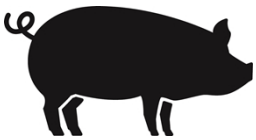
Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml (10 doses) lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enterisol Ileitis lyophilisate for oral suspension



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (2 ml):
Live attenuated *Lawsonia intracellularis* (MS B3903)

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

20 ml (10 doses)

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted, use within 4 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING OF THE SOLVENT

20 ml, 100 ml, 200 ml solvent

1. NAME OF THE SOLVENT

Solvent for Enterisol Ileitis

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

20 ml
100 ml
200 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

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

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
Enterisol Ileitis, lyophilisate and solvent for oral suspension for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer for batch release:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Below information to be added only if the MAH is different: UK, FR
Manufacturer for batch release:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enterisol Ileitis lyophilisate and solvent for oral suspension for pigs

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

Each dose (2 ml) contains:

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

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

4. INDICATION(S)

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. ADVERSE REACTIONS

None known.

If you notice anyside 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

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.
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.

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

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 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 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 PERIOD(S)

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 the abbreviation EXP.

12. SPECIAL WARNING(S)

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 “Interactions”).

Efficacy of revaccination is unknown.

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.

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

Interactions 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 (symptoms, emergency procedures, antidotes)
No adverse reactions have been observed following administration of 10 times the recommended dose.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

November 2020

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

ATC Vet code: QI09AE04 (immunologicals for Suidae, live bacterial vaccines for pigs, *Lawsonia*)

Pack sizes:
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.

Enterisol Ileitis is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under license.

Below information to be added only in case a representative of the MAH is mentioned, depending on national requirements.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Representative of the marketing authorisation holder:
To be either completed nationally or left blank.

Approved 04 March 2021