

# Enterisol® Ileitis Data Sheet

V

chlorobutyl stopper with lacquered aluminium seal.  
High density polyethylene vial containing 20ml (10 doses), 100ml (50 doses), 200ml (100 doses) and 12 x 200ml (12 x 100 doses) closed with a chlorobutyl stopper with lacquered aluminium seal.

Not all pack sizes may be marketed.

## Marketing authorisation holder

Boehringer Ingelheim Limited  
Ellesfield Avenue  
Bracknell Berkshire  
RG12 8YS UK.

## Marketing authorisation no:

Vm 00015/4073, VPA 10007/41/1

## Presentation

Lyophilisate and diluent for oral suspension.  
One 2 ml dose of reconstituted vaccine contains *Lawsonia intracellularis*. At least  $1 \times 10^{4.9}$  TCID<sub>50</sub> Maximum  $1 \times 10^{6.1}$  TCID<sub>50</sub>  
(\*Tissue Culture Infective Dose)

## Uses

For active immunisation of weaned pigs from three weeks of age to reduce intestinal lesions caused by *Lawsonia intracellularis* infection and to reduce growth variability and impairment of weight gain associated with the disease. Under field conditions, the improvement in average daily weight gain (ADG) was seen to be up to 30g/day when vaccinated pigs were compared to non-vaccinates. Onset of protection occurs as early as three weeks post vaccination and lasts for at least 17 weeks.

## Dosage 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 diluent:

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

100 dose presentation: Reconstitute the vaccine by adding half of the content of the accompanying diluent to the vaccine. Shake well and transfer the suspension back into the diluent bottle, mix with the remaining diluent to make up the full amount of 200 ml. Shake well and use immediately.

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

Vaccination via the drinking water: Water systems have to be cleaned and rinsed with untreated water to eliminate residues of

antimicrobials, detergents or disinfectants. The final solution containing the vaccine should be consumed within four hours after preparation. Calculate the number of vials required to vaccinate all the pigs according to the table below:

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

Dilute the vaccine in the drinking water which will be consumed during a four hour time period. This should be calculated on the basis of the water intake observed during a four hour period at the time of planned vaccination on the previous day. 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.

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 2.5g/litre. The final concentration of sodium thiosulfate should be approximately 0.055g/l.

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

#### **Contra-indications, Warnings, etc.**

None known. Do not mix with any other vaccine/immunological product, antibiotics or antimicrobial products. No information is available on the safety and efficacy of the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines are administered within 14 days before or after vaccination with the product. Avoid accidental contact with skin. In the event of accidental skin contact, wash with soap or antibacterial wash and rinse well. No undesirable effects were observed after administration

of the vaccine in breeding and pregnant animals. Vaccinate only clinically healthy animals.

**Special warnings:** The vaccine has not been tested in breeding boars, therefore do not vaccinate breeding boars. Do not vaccinate animals which are receiving treatment with antimicrobials effective against *Lawsonia spp.* Such antimicrobials should be withheld for a minimum of three days before and three days after the day of vaccination. 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 three days post vaccination in faecal samples of more than half of vaccinated animals, therefore transmission to pen-mates can not be excluded in this time period. Efficacy of revaccination is unknown.

#### **Withdrawal period**

Zero days.

#### **Pharmaceutical Precautions**

Store and transport between +2°C and +8°C. Do not freeze.

Use immediately after reconstitution.

Administration of the vaccine should be completed within four hours.

Keep out the reach and sight of children.

For animal treatment only.

#### **Special Precautions for Disposal**

Any unused product or waste material should be disposed of in accordance with national procedures.

**Legal Category** POM

#### **Package Quantities**

##### Vaccine lyophilisate:

Type 1 amber glass vial of 20ml (10 doses), 100ml (50, 100 doses) and 12 x 100 ml (12 x 100 doses) closed with a bromobutyl stopper with lacquered aluminium seal.

##### Vaccine diluent:

Type 1 clear glass vial containing 20ml (10 doses), 100ml (50 doses), 200ml (100 doses) and 12 x 200 ml (12 x 100 doses) closed with a