1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neocolipor suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Per dose of 2 ml:

E. coli adhesin F4 (F4ab, F4ac, F4ad), at least.....2.1 SA.U*
E. coli adhesin F5, at least.....1.7 SA.U*
E. coli adhesin F6, at least.....1.4 SA.U*
E. coli adhesin F41, at least.....1.7 SA.U*

*: [1] SA.U: quantity sufficient to obtain an agglutinating antibody titre of 1 log10 in the guinea pig.
Adjuvant:
Aluminium (as hydroxide) .....1.4 mg

Excipients:
Thiomersal.....0.2 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts).

4.2 Indications for use specifying the target species

Reduction of neonatal enterotoxicosis of piglets, caused by E. coli strains, expressing the adhesins F4ab, F4ac, F4ad, F5, F6 and F41, during the first days of life.

4.3 Contraindications

None.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

- Since the protection of piglets is ensured by colostrum intake, each piglet should ingest a sufficient quantity of colostrum within 6 hours of birth.
- Vaccinate only healthy animals.
- Do not administer in conjunction with other medicinal products.

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

In the case of accidental self-injection, seek medical advice immediately and show the package insert or label to a physician.

Wash and disinfect hands after use.

4.6 Adverse reactions (frequency and seriousness)

Vaccination may cause a slight hyperthermia (less than 1.5°C during a maximum period of 24 hours).

4.7 Use during pregnancy, lactation or lay

No special precautions.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated

4.9 Amounts to be administered and administration route

Shake the vial vigorously before use.
Use sterile syringe and needles. Administer using aseptic procedures.

One 2 ml dose intramuscularly in the neck in the area behind the ear, according to the following schedule:

Primary vaccination:

First injection: 5 to 7 weeks before farrowing
Second injection: 2 weeks before farrowing.

Revaccination:

1 injection 2 weeks before each subsequent farrowing.

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

No undesirable effects have been observed after the administration of twice the recommended dosage.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI09AB02

The vaccine contains the inactivated strains of *E. coli* expressing the adhesins F4ab, F4ac, F4ad, F5, F6 and F41, which cause neonatal enterotoxicosis in piglets, in aluminium hydroxide adjuvant. In sows and gilts, the vaccine induces the specific seroconversion of vaccinated animals; piglets are passively immunised by intake of colostrum and milk containing adhesin-specific antibodies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Aluminium hydroxide
Sodium chloride

6.2 Major incompatibilities

Do not mix with any other vaccine.

6.3 Shelf life

Shelf-life: 18 months at 2 - 8 °C.
Broached vial: 3 hours.

6.4 Special precautions for storage

Store and transport at 2°C - 8°C, protected from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Box of 5-dose 10 ml vial (glass type I vial with butyl rubber stopper).
Box of 10-dose 20 ml vial (glass type I vial with butyl rubber stopper).
Box of 25-dose 50 ml vial (glass type I vial with butyl rubber stopper).
Box of 50-dose 100 ml vial (glass type I vial with butyl rubber stopper).

Not all pack 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 products should be disposed of in accordance with the local requirements

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/93/008/001-004

9. DATE OF FIRST RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14/04/2003
Date of last renewal: 11/03/2008

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.