ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 TOULOUSE
FRANCE

Manufacturer responsible for batch release

Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 SAINT PRIEST
FRANCE

Manufacturing authorisation issued by the French Ministère des Affaires Sociales, Ministère délégué à la Santé, and the Ministère de l'Agriculture et de la Forêt on 31 March 1992.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Annex II of Council Regulation (EEC) No 2377/90

Pharmacologically active substance(s)	Animal species	Other provisions
Aluminium hydroxide[1]	All food producing species	
Thiomersal[2]	All food producing species	For use only as a preservative in multidose vaccines at a concentration not exceeding 0.02%
Sodium hydroxide[3]	All food producing species	
Sodium chloride[4]	All food producing species	
Hydrochloric acid[5]	All food producing species	For use as excipient

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Not applicable.

[1] OJ No L 290 of 05.12.95
[2] OJ No L 110 of 26.04.97
[3] OJ No L 272 of 25.10.96
[4] OJ No L 290 of 05.12.95
[5] OJ No L 143 of 27.06.95

ANNEX III

LABELLING AND PACKAGE INSERT

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neocolipor suspension for injection

2. STATEMENT OF 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.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

5 doses = 10 ml vial.
10 doses = 20 ml vial.
25 doses = 50 ml vial.
250 doses =100 ml vial.

5. TARGET SPECIES

Pigs (sows and gilts)

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Shake the vial vigorously prior to use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Store and transport between 2ºC and 8ºC, protected from light. Do not freeze.
Shelf life of broached vial: 3 hours.

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

Read the package leaflet before use.

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 Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/98/008/001	10 ml vial.
EU/2/98/008/002	20 ml vial.
EU/2/98/008/003	50 ml vial.
EU/2/98/008/004	100 ml vial.

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neocolipor
Suspension for injection
Pigs (sows and gilts)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Adhesins: F4 (F4ab, F4ac, F4ad), F5, F6, F41
Aluminium adjuvant

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

2 ml = 1 dose 5d	10 ml vial
2 ml = 1 dose 10 d	20 ml vial
2 ml = 1 dose 25 d	50 ml vial

4. ROUTE(S) OF ADMINISTRATION

Intramuscular injection

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Read the package leaflet before use.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neocolipor
Suspension for injection
Pigs (sows and gilts)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose of 2 ml:
Adhesins:

F4 (F4ab, F4ac, F4ad), at least ..... 2.1 SA.U*

F5, at least ..... 1.7 SA.U*

F6, at least ..... 1.4 SA.U*

F41, at least ..... 1.7 SA.U*

*: SA.U: quantity sufficient to obtain an agglutinating antibody titre of 1 $\log_{10}$ in the guinea pig.

Adjuvant:
Aluminium (as hydroxide) ..... 1.4 mg

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

50 doses 100 ml vial

4. ROUTE(S) OF ADMINISTRATION

Intramuscular injection

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Shake vigorously prior to use
Read the package leaflet before use.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Neocolipor

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

MARKETING AUTHORISATION HOLDER
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

MANUFACTURER FOR THE BATCH RELEASE
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 SAINT PRIEST
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neocolipor suspension for injection

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

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 $\log_{10}$ in the guinea pig.
Adjuvant:
Aluminium (as hydroxide) ..... 1.4 mg

4. INDICATION(S)

Adjuvanted inactivated vaccine for the reduction of neonatal enterotoxicosis of piglets, caused by E. coli strains, expressing the adhesins F4ab, F4ac, F4ad, F5, F6 and F41.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (sows and gilts)

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

One 2 ml dose 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.

9. ADVICE ON CORRECT ADMINISTRATION

Intramuscular injection in the neck in the area behind the ear.

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

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport at 2°C - 8°C, protected from light. Do not freeze.
Shelf life of broached vial: 3 hours.

12. SPECIAL WARNING(S)

- 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.

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.

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.

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

Do not mix with any other vaccine.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

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.

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.

Veterinary medicinal product subject to prescription.