ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Ibraxion emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Each dose of 2 ml contains:
gE deleted inactivated IBR virus, at least ..... 0.75 VN.U*
* VN.U: Vironeutralising antibody titre after vaccine injection in guinea pigs.

Adjuvant
light paraffin oil ..... 449.6 to 488.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Active immunisation of cattle to reduce the clinical signs of infectious bovine rhinotracheitis (IBR) and field virus excretion.

Onset of immunity: 14 days
Duration of immunity: 6 months

4.3 Contraindications

None

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy animals.

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

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

The injection of the vaccine may cause a transient tissue reaction at the site of injection, which may persist for three weeks and rarely up to five weeks.

The vaccination may cause a slight rise in body temperature (less than 1°C) for a transient period (less than 48 hours after injection) without any consequence to the health or performance of the animal.

A hypersensitivity reaction may occur. These are rare and an appropriate symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Bovalto Ibraxion can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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

Administer one dose (2 ml) by subcutaneous injection in the neck (at the front of the shoulder) according to the following regimen:

The presence of maternally derived antibodies against infectious bovine rhinotracheitis virus may interfere with the vaccination and requires an appropriate vaccination regimen.

Basic vaccination:	two injections 21 days apart. For use in animals from the age of 2 weeks in the absence of maternally derived antibodies against IBR virus or from the age of 3 months in the presence of maternally derived antibodies.
Revaccination:	a booster injection should be administered at 6 month intervals.

Shake well prior to use.
Allow the vaccine to reach a temperature of 15°C-25°C.
Use sterile syringes and needles

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

No undesirable effects other than those mentioned in section 4.6 have been observed after the administration of an overdose.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals, bovine rhinotracheitis virus (IBR)
ATCvet code: QI02AA03

Bovalto Ibraxion is a gene specific deleted (gE), inactivated and adjuvanted (o/w emulsion) vaccine which acts by the active immunisation of cattle characterised by the production of Infectious Bovine Rhinotracheitis (IBR) vironeutralising antibodies.

The gE gene deletion allows differentiation between animals vaccinated with gE-negative vaccines (anti gE antibody negative, IBR vironeutralising antibody positive) and naturally infected animals (positive to both IBR vironeutralising antibody and anti gE antibody). Bovalto Ibraxion can therefore be used as a marker vaccine in association with an appropriate diagnostic test.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light paraffin oil
Benzyl alcohol
Triethanolamine
Polyoxyethylene oleate
Polyoxyethylene oleic alcohol
Potassium chloride,
Sodium chloride,
Potassium dihydrogen phosphate,
Disodium phosphate dihydrate,
Magnesium chloride,
Calcium chloride

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after first opening the immediate packaging: 6 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

Type I glass bottles with a Nitrile elastomer closure and sealed with an aluminium cap
Cardboard box with 1 or 10 bottles of 5 doses (1 x 10 ml or 10 x 10 ml)
Cardboard box with 1 or 10 bottles of 10 doses (1 x 20 ml or 10 x 20 ml)
Cardboard box with 1 or 10 bottles of 25 doses (1 x 50 ml or 10 x 50 ml)

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 local requirements.

7. MARKETING AUTHORISATION HOLDER

MERIAL
29 avenue Tony Garnier
69007 LYON
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/99/017/001-006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09/03/2000
Date of last renewal: 23/03/2010

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

The manufacture, import, possession, sale, supply and/or use of Bovalto Ibraxion may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and/or use Bovalto Ibraxion must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURRER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

MERIAL,Laboratoire Lyon Gerland
254, Avenue Marcel Mérieux-69007 Lyon
FRANCE

Name and address of the manufacturer responsible for batch release

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation-69800 Saint Priest
FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.
According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of national programmes for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) 470/2009.

The excipients, including adjuvants, listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

5 doses (10 ml)
10 x 5 doses (10 x 10 ml)
10 doses (20 ml)
10 x 10 doses (10 x 20 ml)
25 doses (50 ml)
10 x 25 doses (10 x 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Ibraxion emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

For 1 dose of 2 ml:
.gE deleted inactivated IBR virus, at least ..... 0.75 VN.U*
.light paraffin oil ..... 449.6 to 488.2 mg
* VN.U: Vironeutralising antibody titre after vaccine injection in guinea pigs

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

5 doses (10 ml)
10 x 5 doses (10 x 10 ml)
10 doses (20 ml)
10 x 10 doses (10 x 20 ml)
25 doses (50 ml)
10 x 25 doses (10 x 50 ml)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use - SC

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use by: 6 hours

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC 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.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

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

MERIAL
29 avenue Tony Garnier
69007 LYON
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/99/017/001 5 doses (10 ml)
EU/2/99/017/004 10 x 5 doses (10 x 10 ml)
EU/2/99/017/002 10 doses (20 ml)
EU/2/99/017/005 10 x 10 doses (10 x 20 ml)
EU/2/99/017/003 25 doses (50 ml)
EU/2/99/017/006 10 x 25 doses (10 x 50 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5 doses (10 ml)
10 doses (20 ml)
25 doses (50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Ibraxion emulsion for injection
Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

For 1 dose of 2 ml: gE deleted inactivated IBR virus, at least .....0.75 VN.U

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

5 doses (10 ml)
10 doses (20 ml)
25 doses (50 ml)

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR

Bovalto Ibraxion emulsion for injection

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

Marketing authorisation holder
MERIAL
29 avenue Tony Garnier -69007 Lyon
France

Manufacturer responsible for batch release
MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation-69800 Saint Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovalto Ibraxion emulsion for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each dose (2 ml) contains:
gE deleted inactivated IBR virus, at least .....0.75 VN.U*
adjuvant: light paraffin oil ..... 449.6 to 488.2 mg
* VN.U: Vironeutralising antibody titre after vaccine injection in guinea pigs.

4. INDICATION(S)

Active immunisation of cattle to reduce the clinical signs of infectious bovine rhinotracheitis (IBR) and field virus excretion.

Onset of immunity: 14 days
Duration of immunity: 6 months.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

The injection of the vaccine may cause a transient tissue reaction at the site of injection, which may persist for three weeks and rarely up to five weeks.
The vaccination may cause a slight rise in body temperature (less than 1°C) for a transient period (less than 48 hours after injection) without any consequence to the health or performance of the animal.
A hypersensitivity reaction may occur. These are rare and an appropriate symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

Cattle

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

Shake well prior to use.Allow the vaccine to reach a temperature of 15 -25ºC.
Use sterile syringes and needles.

Administer one dose (2 ml) by subcutaneous injection in the neck (at the front of the shoulder), according to the following regimen:
The presence of maternally derived antibodies against infectious bovine rhinotracheitis virus may interfere with the vaccination and requires an appropriate vaccination regimen.

Basic vaccination:
Two injections 21 days apart. For use in animals from the age of 2 weeks in the absence of maternally derived antibodies against IBR virus or from the age of 3 months in the presence of maternally derived antibodies.

Revaccination: a booster injection should be administered at 6 month intervals.

9. ADVICE ON CORRECT ADMINISTRATION

See above.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children
Store and transport refrigerated (2°C- 8°C).
Do not freeze.
Protect from light.
Shelf life after first opening the container: 6 hours
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccinate only healthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy and lactation:
Bovalto Ibraxion can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
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:
No undesirable effects other than those mentioned in the “Adverse reactions” section have been observed after the administration of an overdose.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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 local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

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

15. OTHER INFORMATION

Bovalto Ibraxion is a gene specific deleted (gE), inactivated and adjuvanted (o/w emulsion) vaccine which acts by the active immunisation of cattle characterised by the production of Infectious Bovine Rhinotracheitis (IBR) vironeutralising antibodies.

The gE gene deletion allows differentiation between animals vaccinated with gE-negative vaccines (anti gE antibody negative, IBR vironeutralising antibody positive) and naturally infected animals (positive to both IBR vironeutralising antibody and anti gE antibody). Bovalto Ibraxion can therefore be used as a marker vaccine in association with an appropriate diagnostic test.

The manufacture, import, possession, sale, supply and/or use of Bovalto Ibraxion may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and/or use Bovalto Ibraxion must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession,sale, supply and/or use.

Type I glass bottles with a Nitrile elastomer closure and sealed with an aluminium cap
Cardboard box with 1 or 10 bottles of 5 doses
Cardboard box with 1 or 10 bottles of 10 doses
Cardboard box with 1 or 10 bottles of 25 doses

Not all pack sizes may be marketed.