ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine (0.05 ml for an in ovo dose or 0.2 ml for a subcutaneous dose) contains:

Active substance:
Live attenuated infectious bursal disease virus (IBDV), strain 1052 …….. $10^{1.48}$ – $10^{2.63}$ PU*
* PU: Potency Units

Excipients:
IBDV-specific antibody solution…….. $2.7x10^{6}$ VNU** of IgY per vial
**VNU: Virus Neutralisation Units

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: brown reddish colour.
Solvent: clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and embryonated chicken eggs.

4.2 Indications for use, specifying the target species

For active immunisation of 1-day-old broiler chicks and embryonated broiler chicken eggs to reduce clinical signs and lesions of the bursa of Fabricius caused by very virulent avian infectious bursal disease virus infection.

The onset of immunity depends on the initial maternally derived antibodies (MDA) level of the batch of chickens and even then will be different for individual chickens. In practice, studies in commercial broiler chickens have shown an onset of immunity from between 24 days of age and 28 days of age.

Onset of immunity: from 24 days of age.
Duration of immunity: up to 43 days of age.

The efficacy of the vaccine has been demonstrated in broilers having an average MDA level from 4,500 to 5,100 ELISA units at hatching.

4.3 Contraindications

Do not use in flocks without MDAs against IBDV.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

This product should only be used after it has been demonstrated that very virulent IBDV strains are epidemiologically relevant in the area of vaccination.

Vaccinated birds may excrete the vaccine strain up to 3 weeks following vaccine take. During this time, contact between the vaccinated chickens and any immunosuppressed or unvaccinated birds should be avoided. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible wild and domestic birds.

It is recommended to vaccinate all chickens on a site at the same time.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash and disinfect hands and equipment after use.
Wash and disinfect hands after handling vaccinated birds or their litter because the virus is excreted by vaccinated birds for up to 3 weeks.
In case of adverse reactions following accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In laboratory studies, lymphocyte depletion was very common, followed by a lymphocyte repopulation and regeneration of the bursa of Fabricius. This depletion does not cause immunosuppression in chickens.

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

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.
Do not use in birds in lay or breeding birds, or within 4 weeks before the start of the laying period.

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

In ovo and subcutaneous use.

It is important to note that the volumes of solvent which must be used to reconstitute the vaccine are different depending on whether the vaccine will be administered in ovo to embryonated eggs, or by subcutaneous injection to 1-day-old chicks. The final concentrations of the vaccines will therefore also differ.

Posology:

By the in ovo route: Administer one single injection of 0.05 ml of the reconstituted vaccine into each chicken egg at 18 days of embryonation.

By the subcutaneous route: Administer one single injection of 0.2 ml of the reconstituted vaccine to each chick at 1 day of age.

Method of administration:

For in ovo administration:

An automated egg injection machine can be used. The instructions for the calibration and use of the equipment should be strictly followed in order to deliver the appropriate dose.

For the reconstitution and administration of the vaccine, use sterile equipment free from any residues of chemical disinfectants.

Calculate and prepare the required volume of the vaccine as per the table below:

Dilutions for in ovo administration (0.05 ml per dose):

Number and content of vaccine vials:	Solvent volume to be used:
4 x 1,000 doses	200 ml
8 x 1,000 doses	400 ml
2 x 2,000 doses	200 ml
4 x 2,000 doses	400 ml
8 x 2,000 doses	800 ml
8 x 2,500 doses	1,000 ml
1 x 4,000 doses	200 ml
2 x 4,000 doses	400 ml
4 x 4,000 doses	800 ml
5 x 4,000 doses	1,000 ml
4 x 5,000 doses	1,000 ml

Reconstitution of the vaccine:

1. Withdraw 2 ml of the solvent and inject into the vial containing the lyophilisate. Mix the contents of the vial by gentle agitation until the contents are completely re-suspended, then withdraw the suspension obtained and inject it into the solvent bag.
2. Rinse the vial with another 2 ml of the solvent/lyophilisate suspension obtained in step 1, and inject it back into the solvent bag.
3. Repeat step 2 to ensure that all the lyophilisate has been transferred into the solvent bag.
4. The reconstituted vaccine is a slightly reddish homogeneous suspension which should be used within 2 hours after reconstitution.

The vaccine (0.05 ml dose) must be injected into the amniotic sac of 18-day-old embryonated broiler chicken eggs.

For subcutaneous administration:

An automated syringe can be used. The instructions for the calibration and use of the equipment should be strictly followed in order to deliver the appropriate dose.

For the reconstitution and administration of the vaccine, use sterile equipment free from any residues of chemical disinfectants.

Calculate and prepare the required volume of the vaccine as per the table below:

Dilutions for subcutaneous administration (0.2 ml per dose):

Number and content of vaccine vials:	Solvent volume to be used:
1 x 1,000 doses	200 ml
2 x 1,000 doses	400 ml
4 x 1,000 doses	800 ml
5 x 1,000 doses	1,000 ml
1 x 2,000 doses	400 ml
2 x 2,000 doses	800 ml
2 x 2,500 doses	1,000 ml
1 x 4,000 doses	800 ml
1 x 5,000 doses	1,000 ml

Reconstitution of the vaccine:

1. Withdraw 2 ml of the solvent and inject into the vial containing the lyophilisate.
   Mix the contents of the vial by gentle agitation until the contents are completely resuspended, then withdraw the suspension obtained and inject it into the solvent bag.
2. Rinse the vial with another 2 ml of the solvent/lyophilisate suspension obtained in step 1, and inject it back into the solvent bag.
3. Repeat step 2 to ensure that all the lyophilisate has been transferred into the solvent bag.
4. The reconstituted vaccine is a slightly reddish homogeneous suspension which should be used within 2 hours after reconstitution.

The vaccine (0.2 ml dose) must be injected under the skin of the neck of the 1-day-old broiler chicks.

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

After the administration of a 10-fold overdose, a mild exudate and slight congestion in the bursa of Fabricius were very commonly observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, domestic fowl, live viral vaccines, avian infectious bursal disease virus (Gumboro disease).
ATCvet code: QI01AD09

To stimulate active immunity against very virulent bursal disease viruses (Gumboro disease) in broiler chickens.

The vaccine contains an intermediate-plus IBDV strain bound to specific IBDV immunoglobulins, forming an immune-complex which is administered through vaccination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Glycine
L-histidine
Sucrose
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Potassium chloride
Sodium chloride

Solvent:
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Potassium chloride
Sodium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the lyophilisate as packaged for sale: 24 months.
Shelf life of the solvent as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Lyophilisate:
Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Protect from light.

Solvent:
Do not store above 25 ºC.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I glass vials closed with Type I bromobutyl stoppers and sealed with aluminium caps containing 1,000 doses, 2,000 doses, 2,500 doses, 4,000 doses or 5,000 doses of the freeze-dried vaccine.

Solvent:
Polypropylene bags containing 200 ml, 400 ml, 800 ml or 1,000 ml.

Package sizes:
Cardboard box with 10 lyophilisate vials containing 1,000 doses.
Cardboard box with 10 lyophilisate vials containing 2,000 doses.
Cardboard box with 10 lyophilisate vials containing 2,500 doses.
Cardboard box with 10 lyophilisate vials containing 4,000 doses.
Cardboard box with 10 lyophilisate vials containing 5,000 doses.

Cardboard box with 10 bags containing 200 ml solvent.
Cardboard box with 10 bags containing 400 ml solvent.
Cardboard box with 10 bags containing 800 ml solvent.
Cardboard box with 10 bags containing 1,000 ml solvent.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN
Tel.: +34 972 43 06 60
Fax: +34 972 43 06 61
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/245/001-005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12/11/2019

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

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

ANNEX II

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

Name and address of the manufacturers of the biological active substance

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 Girona
Spain

Laboratorios Hipra, S.A.
Carretera C-63 km 48.300
Polígono Industrial El Rieral
Amer, 17170 Girona
Spain

Name and address of the manufacturer responsible for batch release

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 Girona
Spain

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

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) No 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

Cardboard boxes (lyophilisate vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate for suspension for injection for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of reconstituted vaccine (0.05 ml for an in ovo dose or 0.2 ml for a subcutaneous dose) contains:

Live attenuated infectious bursal disease virus (IBDV), strain 1052….. $10^{1.48}$ – $10^{2.63}$ PU*
* PU: Potency Units

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection.

4. PACKAGE SIZE

10 x 1,000 doses
10 x 2,000 doses
10 x 2,500 doses
10 x 4,000 doses
10 x 5,000 doses

5. TARGET SPECIES

Chickens and embryonated chicken eggs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In ovo or subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/245/001 (10 x 1,000 doses)
EU/2/19/245/002 (10 x 2,000 doses)
EU/2/19/245/003 (10 x 2,500 doses)
EU/2/19/245/004 (10 x 4,000 doses)
EU/2/19/245/005 (10 x 5,000 doses)

17. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate for suspension for injection for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (0.05 ml for in ovo or 0.2 ml for SC) contains:

Live attenuated IBDV, strain 1052…….. $10^{1.48}$ – $10^{2.63}$ PU*
* PU: Potency Units

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

1,000 doses
2,000 doses
2,500 doses
4,000 doses
5,000 doses

4. ROUTE(S) OF ADMINISTRATION

In ovo or SC use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes (solvent bags)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for GUMBOHATCH

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

Solvent for suspension for injection.

4. PACKAGE SIZE

10 x 200 ml
10 x 400 ml
10 x 800 ml
10 x1,000 ml

5. TARGET SPECIES

Chickens and embryonated chicken eggs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In ovo or subcutaneous use.
Read the package leaflet supplied with the lyophilisate vial before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet supplied with the lyophilisate vial before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

Disposal: read package leaflet supplied with the lyophilisate vial.

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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Solvent bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for GUMBOHATCH

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

Solvent for suspension for injection.

4. PACKAGE SIZE

200 ml
400 ml
800 ml
1,000 ml

5. TARGET SPECIES

Chickens and embryonated chicken eggs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In ovo or subcutaneous use.
Read the package leaflet supplied with the lyophilisate vial before use.

8. WITHDRAWAL PERIOD

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet supplied with the lyophilisate vial before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 ºC.

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

Disposal: read package leaflet supplied with the lyophilisate vial.

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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
GUMBOHATCH lyophilisate and solvent for suspension for injection for chickens

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 responsible for batch release:
Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer 17170 (Girona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUMBOHATCH lyophilisate and solvent for suspension for injection for chickens

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

Each dose of reconstituted vaccine (0.05 ml for an in ovo dose or 0.2 ml for a subcutaneous dose) contains:

Active substance:
Live attenuated infectious bursal disease virus (IBDV), strain 1052…….. $10^{1.48}$ - $10^{2.63}$ PU*
* PU: Potency Units

Excipients:
IBDV-specific antibody solution……$2.7x10^{6}$ VNU** of IgY per vial
**VNU: Virus Neutralisation Units

Lyophilisate: brown reddish colour.
Solvent: clear colourless solution.

4. INDICATION(S)

For active immunisation of 1-day-old broiler chicks and embryonated broiler chicken eggs to reduce clinical signs and lesions of bursa of Fabricius caused by very virulent avian infectious bursal disease virus infection.

The onset of immunity depends on the initial maternally derived antibodies (MDA) level of the batch of chickens and even then will be different for individual chickens. In practice, studies in commercial broiler chickens have shown an onset of immunity from between 24 days of age and 28 days of age.

Onset of immunity: from 24 days of age.
Duration of immunity: up to 43 days of age.

The efficacy of the vaccine has been demonstrated in broilers having an average MDA level from 4,500 to 5,100 ELISA units at hatching.

5. CONTRAINDICATIONS

Do not use in flocks without MDAs against IBDV.

6. ADVERSE REACTIONS

In laboratory studies, lymphocyte depletion was very common after vaccine take, which was followed by a lymphocyte repopulation and regeneration of the bursa of Fabricius. This depletion does not cause immunosuppression in chickens.

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

If you notice any side 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

Chickens and embryonated chicken eggs.

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

Posology:

By the in ovo route: Administer one single injection of 0.05 ml of the reconstituted vaccine into each chicken egg at 18 days of embryonation.

By the subcutaneous route: Administer one single injection of 0.2 ml of the reconstituted vaccine to each chick at 1 day of age.

Method of administration:

For in ovo administration:

An automated egg injection machine can be used. The instructions for the calibration and use of the equipment should be strictly followed in order to deliver the appropriate dose.

For the reconstitution and administration of the vaccine, use sterile equipment free from any residues of chemical disinfectants.

Calculate and prepare the required volume of the vaccine as per the table below:

Dilutions for in ovo administration (0.05 ml per dose)

Number and content of vaccine vials:	Solvent volume to be used:
4 x 1,000 doses	200 ml
8 x 1,000 doses	400 ml
2 x 2,000 doses	200 ml
4 x 2,000 doses	400 ml
8 x 2,000 doses	800 ml
8 x 2,500 doses	1,000 ml

1 x 4,000 doses	200 ml
2 x 4,000 doses	400 ml
4 x 4,000 doses	800 ml
5 x 4,000 doses	1,000 ml
4 x 5,000 doses	1,000 ml

Reconstitution of the vaccine:

1. Withdraw 2 ml of the solvent and inject into the vial containing the lyophilisate.
   Mix the contents of the vial by gentle agitation until the contents are completely resuspended, then withdraw the suspension obtained and inject it into the solvent bag.
2. Rinse the vial with another 2 ml of the solvent/lyophilisate suspension obtained in step 1, and inject it back into the solvent bag.
3. Repeat step 2 to ensure that all the lyophilisate has been transferred into the solvent bag.
4. The reconstituted vaccine is a slightly reddish homogeneous suspension which should be used within 2 hours after reconstitution.

The vaccine (0.05 ml dose) must be injected into the amniotic sac of 18-day-old embryonated broiler chicken eggs.

For subcutaneous administration:

An automated syringe can be used. The instructions for the calibration and use of the equipment should be strictly followed in order to deliver the appropriate dose.

For the reconstitution and administration of the vaccine, use sterile equipment free from any residues of chemical disinfectants.

Calculate and prepare the required volume of the vaccine as per the table below:

Dilutions for subcutaneous administration (0.2 ml per dose)

Number and content of vaccine vials:	Solvent volume to be used:
1 x 1,000 doses	200 ml
2 x 1,000 doses	400 ml
4 x 1,000 doses	800 ml
5 x 1,000 doses	1,000 ml
1 x 2,000 doses	400 ml
2 x 2,000 doses	800 ml
2 x 2,500 doses	1,000 ml
1 x 4,000 doses	800 ml
1 x 5,000 doses	1,000 ml

Reconstitution of the vaccine:

1. Withdraw 2 ml of the solvent and inject into the vial containing the lyophilisate.
   Mix the contents of the vial by gentle agitation until the contents are completely resuspended, then withdraw the suspension obtained and inject it into the solvent bag.
2. Rinse the vial with another 2 ml of the solvent/lyophilisate suspension obtained in step 1 and transfer it back into the solvent bag.
3. Repeat step 2 to ensure that all the lyophilisate has been transferred into the solvent bag.
4. The reconstituted vaccine is a slightly reddish homogeneous suspension which should be used within 2 hours after reconstitution.

The vaccine (0.2 ml dose) must be injected under the skin of the neck of the 1-day-old broiler chicks.

9. ADVICE ON CORRECT ADMINISTRATION

It is important to note that the volumes of solvent which must be used to reconstitute the vaccine are different depending on whether the vaccine will be administered in ovo to embryonated eggs, or by subcutaneous injection to 1-day-old chicks. The final concentrations of the vaccines will therefore also differ.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Lyophilisate:
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent:
Do not store above 25 °C.

Shelf life after reconstitution according to directions: 2 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
This product should only be used after it has been demonstrated that very virulent IBDV strains are epidemiologically relevant in the area of vaccination.
Vaccinate healthy animals only.
It is recommended to vaccinate all chickens on a site at the same time.
Vaccinated birds may excrete the vaccine strain up to 3 weeks following vaccine take. During this time, contact between the vaccinated chickens and any immunosuppressed or unvaccinated birds should be avoided.
Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible wild and domestic birds.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after use.
Wash and disinfect hands after handling vaccinated birds or their litter because the virus is excreted by vaccinated birds for up to 3 weeks.
In case of adverse reactions following accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Lay:
The safety of the veterinary medicinal product has not been established during lay.
Do not use in birds in lay or breeding birds, or within 4 weeks before the start of the laying period.

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 (symptoms, emergency procedures, antidotes):
After the administration of a 10-fold overdose mild exudate and slight congestion in the bursa of Fabricius were very commonly observed.

Incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with this 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 or pharmacist 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

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

Package sizes:

Cardboard box with 10 lyophilisate vials containing 1,000 doses.
Cardboard box with 10 lyophilisate vials containing 2,000 doses.
Cardboard box with 10 lyophilisate vials containing 2,500 doses.
Cardboard box with 10 lyophilisate vials containing 4,000 doses.
Cardboard box with 10 lyophilisate vials containing 5,000 doses.

Cardboard box with 10 bags containing 200 ml solvent.
Cardboard box with 10 bags containing 400 ml solvent.
Cardboard box with 10 bags containing 800 ml solvent.
Cardboard box with 10 bags containing 1,000 ml solvent.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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