Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIMUNE 302 ND+IB+EDS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.3-ml dose of vaccine contains:

Active substances:

Inactivated Newcastle Disease virus, Ulster 2C strain, at least	$50PD_{50}$ [1]
Inactivated Infectious Bronchitis virus, Mass41 strain, at least	18 HI.U
Inactivated Egg Drop Syndrome virus (EDS76), V127 strain, at least	180 HI.U

The concentrations are expressed by the antibody titre obtained during the potency test. One unit (U) corresponding to an antibody titre of 1.
HI: haemaglutination inhibiting
[1]: Minimum protective dose according to monograph 0870 of Ph. Eur.

Adjuvant(s):

Paraffin oil	170 to 186 mg

Excipient(s):

Thiomersal, at most	30 µg
Formaldehyde, at most	43.2 µg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Water-in oil emulsion for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (breeder and layer pullets).

4.2 Indications for use, specifying the target species

Booster immunisation of breeder and layer pullets after vaccination with live vaccines against:
. Newcastle Disease virus, in order to reduce egg drop linked to Newcastle Disease infection,
. Infectious Bronchitis virus, in order to reduce egg drop linked to Infectious Bronchitis infection caused by the Mass41 strain.
Active immunisation of breeder and layer pullets in order to reduce egg drop linked to infection with Egg Drop Syndrome virus EDS76 without priming.

Onset of immunity: 4 weeks after vaccination.
Duration of immunity: one laying period.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Vaccinate only healthy animals.

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

To the user:

This 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 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)

No palpable reactions were observed following the injection of one dose of vaccine. In clinical studies, lesions linked to the oily adjuvant were observed histologically three weeks after injection in 87% of cases, e.g. small quantities of oily residues and occasional aseptic micro-abscesses.

4.7 Use during pregnancy, lactation or lay

Not to be used within 2 weeks before the onset of the laying and during the laying period.

4.8 Interaction with other medicinal products and other forms of interactions

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 (0.3-ml) by intramuscular route from the age of 18 weeks and at least 4 weeks after the priming with live vaccines against Newcastle Disease (strain Hitchner B1 or VG/GA) and Infectious Bronchitis (strain Mass H120).

Shake well before use.
Apply usual aseptic procedures.
Do not use syringes with natural rubber or butyl elastomer pistons.
Equipment including needles and syringes must be sterile before use.

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

In addition to the adverse effects mentioned in paragraph «Adverse reactions (frequency and seriousness)», transitory apathy and slight oedema at injection site may occur after the administration of a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QI01AA13
Inactivated vaccine in oily adjuvant against Newcastle Disease, Infectious Bronchitis and Egg Drop Syndrome (EDS76).

The vaccine stimulates active immunity of breeder and layer pullets against Egg Drop Syndrome (EDS76) (without priming), Newcastle Disease and Infectious Bronchitis, subsequent to priming with live vaccines against these diseases.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin oil
Thiomersal

6.2 Major incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf-life

Shelf-life: 18 months.
Use immediately after opening.

6.4 Special precautions for storage

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Nature of primary packaging elements:
- Polypropylene bottle
- Nitrile elastomer closure

- Aluminium cap

Sales presentations:

150-ml (500-dose) bottle.
150-ml (500-dose) bottle, box of 10 bottles.
300-ml (1,000-dose) bottle.
300-ml (1,000-dose) bottle, box of 10 bottles.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/051/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 November 2005
Date of last renewal: 28 July 2009

10 DATE OF REVISION OF THE TEXT

December 2018