1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIMUNE 303 ND+IB+ART*
* for all countries except Austria, Belgium, Denmark and Sweden.
Emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.3-ml dose 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 Avian Rhinotracheitis virus (Swollen Head Syndrome), VCO3 strain, at least 0.76 ODD (culture substrate: hen eggs, Vero cells)*
The concentrations are expressed by the antibody titre obtained during the potency test. One unit (U) corresponding to an antibody titre of 1.
HI: haemagglutination inhibiting - ODD : Optical Density Difference
(1): Minimum protective dose according to monograph 0870 of Ph. Eur.
*: for Germany only

Adjuvant(s):
Paraffin oil .....170 to 186 mg

Excipient(s):
Thiomersal, at most .....30 µg
Formaldehyde, at most .....45 µg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Whitish homogeneous 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 Mass 41 strain,
- Avian pneumovirus in order to reduce respiratory signs linked to avian pneumovirus infection (Avian Rhinotracheitis).

Newcastle Disease and Infectious Bronchitis components:
- onset of immunity: 4 weeks after vaccination,
- duration of immunity: one laying period.

Avian Rhinotracheitis component:

- onset of immunity: 14 weeks after vaccination,
- duration of immunity: one laying period.

4.3 Contraindications

None

4.4 Special warnings

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.
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)

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

Do not use in birds in lay and 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

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), Infectious Bronchitis (strain Mass H120), and avian pneumovirus (strain PL21).

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

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. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI01AA21
Inactivated vaccine in oily adjuvant against Newcastle Disease, Infectious Bronchitis and Avian Rhinotracheitis.

The vaccine stimulates active immunity of breeder and layer pullets against Newcastle Disease, Infectious Bronchitis and Avian Rhinotracheitis (Swollen Head Syndrome), subsequent to priming with live vaccines against these diseases.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Paraffin oil
- Thiomersal.
- Formaldehyde.
- Ester of fatty acids and ethoxylated polyols.
- Ester of fatty acids and polyols.
- Water for injections.

6.2 Major incompatibilities

Do not mix with any other vaccine/immunological 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: use immediately.

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

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.

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 product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

PROHIBITION OF SALE, SUPPLY AND/OR USE
Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.