SUMMARY OF PRODUCT FEATURES

1. Name of the veterinary medicinal product

GUMBOPEST

2. Qualitative and quantitative composition

A dose of 0.3 ml contains:

Active substance(s):

Inactivated avian infectious bursal disease virus, ... VNJO strain	>= 5 DP_{50} (*)
Inactivated Newcastle disease virus, ... Ulster strain	>= 50 DP_{50} (*)

Excipient(s):

Paraffin oil	170 - 186 mg
Thiomersal	0.015 mg

(*) DP_{50} = QS to obtain in the vaccinated animal a protective dose of 50% inhibiting haemagglutination.

For the full list of excipients, see section “List of excipients”

3. Pharmaceutical form

Injectable emulsion

4. Clinical information

4.1. Target species

Chickens.

4.2. Indications for use, specifying the target species

In future laying and breeding hens:

- Active immunization against avian infectious bursal disease (Gumboro disease) and Newcastle disease as a booster of the respective live vaccines.

4.3. Contraindications

Not known.

4.4. Specific warnings for each target species

None.

4.5. Special precautions for use

i) Special precautions for use in animals

Vaccinate only healthy animals.
Observe the usual aseptic conditions.
Do not use a syringe with an elastomer piston made from natural rubber or butyl derivatives.

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

To the user:
This product contains mineral oil. Its accidental injection in humans can cause significant 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 intervention is not provided.
If you are the victim of an accidental injection of the product, seek medical advice promptly, even if the injected dose is very small, and have the leaflet with you.
If the pain persists for more than 12 hours after medical examination, seek medical advice again.

To the attending physician:
This product contains mineral oil. Even if the quantity of product injected is really minimal, accidental injection of this product containing oil can cause significant swelling, which can, for example, lead to necrotizing ischemia and the loss of a finger. A thorough and PROMPT surgical examination is required and may require early incision and irrigation of the injection site, especially when the fingertip or tendon is involved.

iii) Other precautions

None.

4.6. Adverse reactions (frequency and severity)

Not known.

4.7. Use during pregnancy, lactation or laying

Do not administer to hens during laying, or within 2 weeks before they start laying.

4.8. Drug interactions and other forms of interaction

No information is available on the safety and efficacy of the combination of this vaccine with any other veterinary medicinal product. Therefore, a decision to use this vaccine before or after another veterinary medicinal product must be made on a case-by-case basis.

4.9. Dosage and route of administration

1 dose of 0.3 ml per animal, subcutaneously or intramuscularly.
A single injection 2 to 4 weeks before the onset of laying.

Shake the bottle vigorously before and periodically during use.

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

Not known.

4.11. Waiting time

Zero days.

5. Immunological properties

ATC-vet code QI01AA11.

The vaccine contains an inactivated strain of avian infectious bursal disease virus (Gumboro disease), an inactivated strain of Newcastle disease virus and an oily adjuvant. It induces active immunity against infection with avian infectious bursal disease virus (Gumboro disease) and against Newcastle disease.

6. Pharmaceutical information

6.1. List of excipients

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

6.2. Major incompatibilities

Do not mix with other medicines.

6.3. Retention period

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.
Use immediately after opening the bottle.

6.4. Special precautions for storage

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

6.5. Nature and composition of primary packaging

150 mL bottle
300 mL bottle

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

Empty packaging and any remaining product must be disposed of in accordance with current practices governed by waste regulations.

7. Marketing authorisation holder

BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE
29 AVENUE TONY GARNIER
69007 LYON
FRANCE

8. Marketing authorisation number(s)

FR/V/3573802 6/1990

150 mL
bottle 300 mL
bottle Box of 10 150 mL bottles
Box of 10 300 mL bottles

Not all presentations may be marketed.

9. Date of first authorization/renewal of authorization

06/15/1990 - 01/28/2022

10. Date of text update

04/01/2023