PARTICULARS TO APPEAR ON THE OUTER PACKAGE (10x1000 dose and 10x2500 dose CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallivac IBD

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Attenuated freeze-dried infectious bursal disease vaccine for chickens (broilers, future layer, broiler breeders)

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. PACKAGE SIZE

10 x 1000 dose vial
10 x 2500 dose vial

5. TARGET SPECIES

Chickens

6. INDICATION(S)

To protect against mortality and reduce lesions associated with Infectious Bursal Disease throughout the rearing period.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Attenuated IBD virus, strain S706, at least 10^4 $CCID_{50}$ per dose.
Oral or spray administration.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

Use immediately after reconstitution.

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

Dispose of waste material in accordance with national requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

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To be supplied only on veterinary prescription.

IE POM

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4192

VPA 10454/057/001

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (1000 dose and 2500 dose VIAL LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallivac IBD

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Attenuated IBD virus

3. PHARMACEUTICAL FORM

Oral or spray administration

4. PACKAGE SIZE

1000 doses vial
2500 doses vial

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Attenuated IBD virus, S706, ≥ 10^4 $CCID_{50}$ per dose.
Oral or spray administration

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Use immediately after reconstitution.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only

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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

Boehringer Ingelheim Animal Health UK Ltd

Boehringer Ingelheim Vetmedica GmbH

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4192

VPA 10454/057/001

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PACKAGE LEAFLET

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

Marketing Authorisation Holder
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer for the batch release
Boehringer Ingelheim Animal Health France SCS
Laboratoire Portes des Alpes
Rue de l'Aviation
69800 Saint Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IBD
Lyophilisate for suspension

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

Each dose of vaccine contains:
Active ingredient:
Infectious Bursal Disease virus,
attenuated strain S706, at least $10^{4.0}$ $CCID_{50}$
Excipient: qs 1 dose

4. INDICATION(S)

Active immunisation of chickens to protect against mortality and to reduce lesions associated with Infectious Bursal (Gumboro) Disease.
Immunity has been demonstrated 2 weeks after the first administration and has been shown under field conditions to persist throughout the rearing period.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy birds.

6. ADVERSE REACTIONS

Laboratory studies have shown that when the vaccine virus was experimentally passed from bird to bird, damage to the bursa increased. This was detected by histological examination of the bursae. However, this is not considered to result in an immunosuppressive effect.

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

7. TARGET SPECIES

Chickens (broilers, future layers and broiler breeders).

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

The choice of vaccination schedule employed should be determined at the discretion of a veterinary surgeon taking into account the historical vaccination program employed, level of IBD field challenge on the farm and level of maternally derived antibody in the birds to be vaccinated (high levels of maternally derived antibodies can interfere with an active immune response to vaccination).
The recommended vaccination schedules are:

Three doses:

- At one day of age in the hatchery, one dose administered to each bird by coarse spray.
- At 9-12 days of age, one dose administered to each bird via the drinking water.
- At 17-25 days of age, one dose administered to each bird via the drinking water.

Two doses:

- At 0-14 days of age, one dose administered to each bird by coarse spray at day old, otherwise via the drinking water.
- At 14-28 days of age, one dose administered to each bird via the drinking water.

Reconstitution should be in plastic, not metal containers. Only sterile antiseptic-free materials should be used for the preparation of vaccine solution.
The freeze-dried vaccine must not be reconstituted with water containing antiseptic or disinfectant.

9. ADVICE ON CORRECT ADMINISTRATION

ADMINISTRATION BY SPRAY
Day-old chicks may be dosed by coarse spray, in their chick boxes in the hatchery. The vaccine should be reconstituted in non-chlorinated drinking water immediately prior to use.
The volume of water to be sprayed per chick box should allow even coverage of the chicks without excessive wetting.
Application can be best carried out in an automatic cabinet, as for Infectious Bronchitis vaccine. The spray nozzle should be adjusted for a coarse spray with separate droplets which can be checked by spraying into an empty chick box. Droplets fall mainly on the head and shoulders, and bright light will facilitate rapid intake by birds preening each other.
Where an automatic cabinet is not available, a garden type spray, producing large droplets, may be used.
ADMINISTRATION IN DRINKING WATER
The vaccine should be reconstituted in the drinking water immediately before use.

The vaccine should be administered to the birds in the drinking water over a 1-2 hour period.
The volume of water required should be calculated according to the water consumption recorded a day or so before vaccination during a 2 hour period at the same period of the day as the scheduled vaccination, and treated with skimmed milk powder at a rate of 2g per litre or 10g per gallon at least 20 minutes prior to reconstituting the vaccine.
The required number of doses should be reconstituted in a small volume of water which has been treated with the milk powder in a clean, disinfectant-free plastic bucket. Once reconstituted, add the vaccine to the drinking water volume previously calculated and mix thoroughly.
Drinker lines should be primed with vaccinated water prior to allowing the birds access to the drinkers.
Birds may be deprived of water for up to one and a half hours prior to vaccination, if necessary, in order to encourage drinking. Activating feeding systems during vaccination will also encourage drinking.

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Shelf life after reconstitution: Use immediately.
Protect from light.
Store and transport refrigerated (2°C-8°C).
Do not freeze.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNINGS

Special precautions for use in animals
Due to the spread of the vaccine virus, it is recommended to separate vaccinated and unvaccinated birds.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
During spray administration, the eyes must be protected by safety goggles and the nose and mouth by a dust mask. A helmet with filtered air circulation may be used instead of goggles and a mask.
Care should be taken during reconstitution of the vaccine and drinking water application. Hands should be washed and disinfected after vaccinating.

Use during pregnancy, lactation or lay
Do not use in birds in lay or within 4 weeks of the onset of lay.

Interaction with other medicinal products and other forms of interaction
No information is available on the safety and efficacy from the concurrent use of this vaccine with any other except Boehringer Ingelheim’s live vaccines against

Newcastle Disease and Infectious Bronchitis. It is therefore recommended that no other vaccines than these should be administered within 14 days before or after vaccination with the product.

Incompatibilities
Do not mix with any other medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2020

15. OTHER INFORMATION

For Animal Treatment Only

To be supplied only on veterinary prescription

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UK		Vm 08327/4192

IE: POM Prescription Only Medicine VPA10454/057/001

Type I glass vials with butyl elastomer closure and aluminium cap, containing 1000, 2000, 2500 or 5000 doses.

Cartons containing 1, 10 or 50 vials of 1000, 2000, 2500 or 5000 doses.

Not all pack sizes may be marketed.

Approved 27 May 2020