

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IBD S706 NEO

Effervescent tablet for use in drinking water for chickens

Live, attenuated avian infectious bursitis virus (S706 strain)

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:

Infectious Bursal Disease virus, attenuated strain S706, $10^{4.0}$ to $10^{5.3}$ CCID₅₀*

* CCID₅₀: Cell Culture Infective Dose 50%

3. PHARMACEUTICAL FORM

Effervescent tablet

4. PACKAGE SIZE

1 blister of 10 tablets of 2,000 doses

1 blister of 10 tablets of 5,000 doses

10 blisters of 10 tablets of 2,000 doses

10 blisters of 10 tablets of 5,000 doses

5. TARGET SPECIES

Chickens (broilers, future layers and broiler breeders).

6. INDICATION(S)

Active immunisation of chickens to protect against mortality and to reduce lesions associated with Infectious Bursal (Gumboro) Disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once dissolved, use within 2 hours

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C-8°C).

Do not keep unused tablets removed from the blister.

Keep the blisters in the outer carton.

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

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

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

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

IE: Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufactured with technology under license from Phibro Animal Health Corporation USA and its affiliates

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4323

17. MANUFACTURER'S BATCH NUMBER
--

Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister of 10 tablets of 2,000 doses
Blister of 10 tablets of 5,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IBD S706 NEO
Effervescent tablet for use in drinking water for chickens

2000 doses
5000 doses



2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim logo

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot> {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

GALLIVAC IBD S706 NEO
Effervescent tablet for suspension

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>:

UK: Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK
IE: Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS
Laboratoire de Porte des Alpes
99 rue de l'aviation
69800 Saint Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IBD S706 NEO
Effervescent tablet for use in drinking water for chickens

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

Per dose:
Infectious Bursal Disease virus, attenuated strain S706, $10^{4.0}$ to $10^{5.3}$ CCID₅₀*
* CCID₅₀: Cell Culture Infective Dose 50%

4. INDICATION(S)

Active immunisation of chickens to protect against mortality and to reduce lesions associated with Infectious Bursal (Gumboro) Disease.

5. CONTRAINDICATIONS

None

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 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 (broilers, future layers and broiler breeders).

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

The vaccination schedule is:

Two doses:

- . At 8-12 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.

However, the choice of vaccination schedule may be adapted by the prescribing 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).

Method of administration: for use in drinking water.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitution should be in plastic, not metal containers. Only sterile antiseptic-free materials should be used for the preparation of vaccine suspension.

The tablet vaccine must not be resuspended with water containing antiseptic or disinfectant.

The vaccine should be resuspended in the drinking water immediately before use.

Wait until complete resuspension of the tablets before using the vaccine suspension.

The reconstituted vaccine is a light yellow suspension, and a thin foam layer may form over the surface.

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 sight and reach of children.

Store and transport refrigerated (2°C-8°C).

Do not keep unused tablets removed from the blister.

Shelf life after suspending according to instructions: 2 hours.

Keep the blisters in the outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Vaccinate healthy animals only.

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:

Care should be taken during resuspension of the vaccine and drinking water application. Hands should be washed and disinfected after vaccinating.

Lay:

Do not use in birds in lay and 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):

No adverse reactions other than those described under section "Adverse Reactions" were observed following the administration of an overdose.

Incompatibilities:

Do not mix with any other medicinal product

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

Ask your veterinary surgeon 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

Date DD/MM/YYYY

<15. OTHER INFORMATION>

For Animal Treatment Only

To be supplied only on veterinary prescription

UK: Vm 08327/4323

IE: VPA XXXXX/XXX/XXX

Box of 1 blister of 10 tablets of 2,000 doses

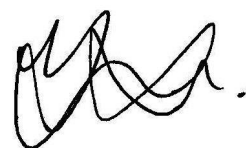
Box of 1 blister of 10 tablets of 5,000 doses

Box of 10 blisters of 10 tablets of 2,000 doses

Box of 10 blisters of 10 tablets of 5,000 doses

Not all pack sizes may be marketed.

Manufactured with technology under license from Phibro Animal Health Corporation
USA and its affiliates



Approved: 15 December 2020