SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GALLIVAC IBD

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active ingredient:
Infectious Bursal Disease virus, attenuated strain S706, at least $10^{4.0}$ $CCID_{50}$

Excipient:
qs 1 dose

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, (broilers, future layers and broiler breeders).

4.2 Indications for use, specifying the target species

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.

4.3 Contra-indications

Do not vaccinate unhealthy birds.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

Due to the spread of the vaccine virus, it is recommended to separate vaccinated and unvaccinated birds.

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

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Not to be used in birds in lay or within 4 weeks of the onset of lay.

4.8 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.

4.9 Amounts to be administered and administration route

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:

<u>Three doses</u>:
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.

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 re-constituting 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.

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

None other than those under section 4.6.

4.11 Withdrawal Period(s)

Zero days.

5. PHARMACOLOGICAL OR IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against IBD infection.

ATC vet code: QI01AD09

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disaccharide
Protein hydrolysate
Salts

6.2 Major incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution: Use immediately.

6.4 Special precautions for storage

Protect from light.
Store and transport refrigerated (2^0C-8^0C).
Do not freeze.

6.5 Nature and composition of immediate packaging

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.

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

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4192

9. DATE OF FIRST AUTHORISATION

16 April 1999

10. DATE OF REVISION OF THE TEXT

27 May 2020

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