LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

IB AMPOULE HATCHPAK IB H120 10,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HatchPak IB H120
IB H120

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 000 doses

4. ROUTE(S) OF ADMINISTRATION

Spray

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

LOT

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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HatchPak IB H120
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2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 000 doses

4. ROUTE(S) OF ADMINISTRATION

Spray

5. WITHDRAWAL PERIOD

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LOT

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EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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B. PACKAGE LEAFLET

PACKAGE LEAFLET

HatchPak IB H120

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

Manufacturer for the batch release:
MERIAL, Laboratoire Porte des Alpes, Rue de l'Aviation, 69800 Saint Priest, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HatchPak IB H120
Frozen suspension for nebuliser suspension. Yellow.

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

Per one reconstituted dose:
Live Infectious Bronchitis virus, H120 strain .....3.7 to 4.7 $\log_{10}$ EID_{50}
* 50 per cent egg infective doses

4. INDICATION(S)

In one day-old chickens:
- active immunisation against Infectious Bronchitis in order to reduce infection with Massachusetts serotype of Infectious Bronchitis virus.

Onset of immunity: 21 days

Duration of immunity: 6 weeks after a single administration.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Bronchial rales, not associated with respiratory distress or any general sign, may be observed between 5 and 14 days after vaccination in up to 15% of the birds.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

One day old chickens.

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

Reconstitution of the vaccine

1. Prepare a container filled with the appropriate quantity of clean non-chlorinated drinking water (7 to 30 ml per box of 100 chicks according to the type of sprayer used in the hatchery).
2. Wear protective gloves and spectacles whilst thawing and opening the ampoules. Maximal precautions when handling liquid nitrogen should be taken. Refer to the section 9. Advice on correct administration.
3. Remove from the liquid nitrogen container only those ampoules carried by a yellow cane which are to be used during the vaccination session.
4. Thaw the contents of the ampoules rapidly by agitation in water at 25-30°C. Proceed immediately to next step.
5. As soon as they are completely thawed, open the ampoules by holding them at arm's length in order to minimise risk of injury should the ampoule break.
6. Once the ampoule is open, draw up the content into a 10-ml sterile syringe.
7. Transfer the suspension into the container containing the appropriate quantity of clean non-chlorinated water prepared at step1.
8. Draw up 5 ml of the contents of the container into the syringe.
9. Rinse the ampoule with these 5 ml, and then transfer the rinsing liquid into the container.
10. Repeat the rinsing operation once or twice.
11. Where HatchPak Avinew (carried by green cane) is to be used concurrently and presented in a second ampoule, carry out again the steps 3 to 10 (opening the ampoule, drawing up vaccine, rinsing the ampoule) with the second ampoule of vaccine. Then, transfer the contents of this second ampoule into the container which has previously been used for the first vaccine.
12. The reconstituted vaccine prepared as described is ready for use. It should be used immediately after preparation and therefore the vaccine suspension should only be prepared as and when required.
13. Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.

Posology

One administration of the product from day-old, via the respiratory route (spray application).

Method of administration

- The vaccine is intended for mass vaccination of chicks in the hatchery, the vaccine solution should be applied as a coarse spray whilst the chicks are in their chick boxes.
- Spray the vaccine solution above the birds using a sprayer that enables production of drops of 100 µm or more that cover the chicks with the vaccine, so the vaccine is administered directly to their eye and the droplets pearls that shine on the down will encourage them to pick them off of each other and from the surface of the box.
- For effective vaccine distribution, make sure that birds are closely confined together during spraying. During and after vaccination ventilation should be switched off in order to avoid turbulences.

9. ADVICE ON CORRECT ADMINISTRATION

- The presence of disinfectant and/or antiseptic in water and material used for the preparation of the vaccine solution is not compatible with effective vaccination.
- Care should be taken when handling during preparation of the vaccine. The cold gas must not be breathed. The manipulation should take place only in well ventilated place to prevent fatal suffocation.
- Wear protective gloves and spectacles whilst thawing and opening the ampoules. Skin contact with liquid nitrogen must be prevented as it can cause tissue freezing, resulting in severe burns.
- Open the ampoules by holding them at arm's length in order to minimise risk of injury should an ampoule break.
- Wash and disinfect hands and equipment after vaccinating.
- For more information, contact the manufacturer.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

- Keep out of the reach and sight of children.
- Store and transport the vaccine in liquid nitrogen (-196°C) and regularly check the level of liquid nitrogen.
- Store the reconstituted vaccine at a temperature lower than 25°C.
- Use immediately after opening the vials and administer within 2 hours after preparation of the vaccine for use.
- Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

- Vaccine viruses can spread to unvaccinated birds. Infection of unvaccinated birds with the vaccine virus from vaccinated birds does not cause any signs of disease. Reversion to virulence trials carried out in the laboratory have shown that the vaccine viruses do not acquire any pathogenic characteristics after at least 5 passages in chickens.
- Vaccinate healthy birds only.
- The vaccine is only intended for use in newly hatched chicks and is not appropriate after the age of one day. The data available on the properties of the strain are not indicative of a detrimental effect on the reproductive tract, in particular the strain is compliant to the specifications of the Ph. Eur. with regard to the safety for the reproductive tract.
- Do not mix with any other medicinal product, except with live frozen vaccine against Newcastle disease containing VG/GA strain.
- No side effects other than those listed in paragraph "Adverse reactions" have been observed following the administration of more than 10 times the recommended dose of vaccine.
- No information is available on the safety and efficacy from the concurrent use of this vaccine with any other except with a frozen live vaccine against Newcastle disease containing VG/GA strain and with a recombinant HVT vaccine expressing the protective antigen of the Infectious Bursal disease virus. It is therefore recommended that no other vaccines than these should be administered within 14 days before or after vaccination with the product.

- The import, sale, supply and/or use of HatchPak IB H120 is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use HatchPak IB H120 must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use of the 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 in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The vaccine contains live Infectious Bronchitis virus, H120 strain. The vaccine stimulates active immunity against Infectious Bronchitis.

10,000-dose ampoule
15,000-dose ampoule
Not all pack sizes may be marketed.

Veterinary medicinal product subject to prescription. For animal treatment only.

Marketing authorisation number:

The information below will be added with a sticker on the leaflet:

Batch Number:

Expiry date:

Approved: 16 November 2018