[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAVIAR-B1 lyophilisate for suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.03 ml dose contains:

Active substance:
Live attenuated Newcastle Disease Virus, strain B1.....$10^{6.5}$ – $10^{7.7}$ EID_{50}*
* 50 % infective dose in chicken embryos

Excipients (included in the solvent for oculonasal administration):
Patent blue V (E-131)…….0.003 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension or for use in drinking water.

Yellowish lyophilisate.
Solvent: Dark blue clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

For active immunisation of chickens (broilers, future layers and breeders) for the prevention of clinical signs and deaths caused by Newcastle disease.

Onset of immunity: 21 days post vaccination
Duration of immunity: 5 weeks after vaccination (based on serological data)

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinated chickens may excrete the vaccine strain up to 14 days following vaccination. During this time, the contact of unvaccinated animals with vaccinated chickens should be avoided. Therefore, all birds at the same facility have to be vaccinated at the same time.

Special precautions should be taken to avoid spreading of the vaccine strain to susceptible species like turkeys.

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

If administered by spray, personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and litter from recently vaccinated chickens.

4.6 Adverse reactions (frequency and seriousness)

Respiratory symptoms may occur in vaccinated birds at 5-7 days post-vaccination very rarely, according to studies performed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.

4.8 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 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.

4.9 Amounts to be administered and administration route

Chickens from 1-day-old (broilers, future layers and breeders): 1 dose/bird.
The veterinary surgeon will establish the most suitable vaccination programme according to the health condition of each farm and area.

Oculo-nasal administration:
Remove the aluminium caps and the stoppers from the vial containing the lyophilisate and the bottle of the solvent. Fix the connector between the vial of the lyophilisate and the bottle of the solvent. Shake gently until complete solution of the lyophilisate. Place the supplied dropper in the bottle and administer one drop of the vaccine (0.03ml) per bird, in the eye or nare using the dropper (30 ml per 1,000 doses).

Drinking water administration:
Remove the aluminium caps and the stopper of the vial containing the lyophilisate. Dissolve the lyophilisate by filling the vial half way with cool fresh tap water free of chlorine, detergents, disinfectants or metal ions. Shake gently until the lyophilisate is completely dissolved and pour the resulting suspension into an adequate container up to a volume of drinking water that can be ingested within 1/2 or 1 hour at most, keeping in mind the age of the birds.
Water should be withheld for 1-2 hours prior vaccination to increase the thirst of the birds depending on the environmental conditions to ensure that all reconstituted vaccine is consumed within 1 to 2 hours

The following volumes are appropriate:

Age of the bird	Approx. amount of water for 1,000 birds
1 to 3 weeks	5 to 10 litres
4 to 9 weeks	12 to 23 litres
10 to 16 weeks	27 to 37 litres

Spray administration:
Validate the spraying device to be used for checking the necessary amount of water, as it totally depends on the type of spraying device used and the size of drops it produces. Check the quantity of water used and this will be the amount that will have to be used to mix with the necessary doses, depending on the number of birds to be vaccinated.
Remove the aluminium caps and the stopper of the vial containing the lyophilisate. Fill the spraying device with cool fresh tap water free of chlorine, detergents, disinfectants or metal ions. The birds are sprayed uniformly with a distance of 30 – 40 cm.

For primary vaccinations in the field usually coarse spray is used (drop size ≥ 100 µm) and for revaccinations usually a droplet size between 50 – 80 µm (fine spray) is used.

The following volumes are appropriate:

No. of doses	1-day-old chicks (large drops)	Older birds (fine drops)
1,000	200-250 ml	500-1000 ml

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

No symptoms other than those indicated in section 4.6 have been observed following administration of tenfold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccines for domestic fowl, Newcastle disease virus (NDV, paramyxovirus 1) .
ATC vet code: QI01AD06
To stimulate active immunity against infection with Newcastle Disease Virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:

Dipotassium hydrogen phosphate
Potassium dihydrogen phosphate
Gelatin
Sucrose
Casein hydrolysate

Solvent (only for oculo-nasal route):
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Patent blue V (E-131)
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after dilution or reconstitution according to directions: use immediately.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Lyophilisate: Type I 10-ml neutral glass vials closed with Type I bromobutyl stoppers and aluminium caps.

Solvent for oculonasal administration: Plastic bottles (MDPE) of 50 ml containing 32 ml of solvent closed with Type I nitrile chlorobutyl stoppers and aluminium caps.

The solvent packaging includes a transfer device and a dropper made of low-density polyethylene (LDPE) for administration by the oculonasal route.

Pack sizes:
Cardboard box with 10 vials of 500, 1,000, 2,500 or 5,000 doses
Cardboard box with 10 vials of 1,000 doses + Cardboard box with 10 bottles of 32 ml of solvent.
Connectors and droppers are included for the administration with the solvent.

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

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

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation (ES): 17/07/1972
Date of last renewal: 16/02/2011

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Dispensation conditions: Medicament by veterinary prescription.
Administration conditions: Administration under veterinary control or supervision.