

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
HIPRAVIAR-B1 lyophilisate for suspension for chickens

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:

LABORATORIOS HIPRA, S.A.

Avda. la Selva, 135

17170 AMER (Girona)

Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAVIAR-B1 lyophilisate for suspension for chickens.

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

Each 0.03 ml dose contains:

Active substance:

Live attenuated Newcastle Disease Virus, strain B1 $10^{6.5} - 10^{7.7}$ EID₅₀*

* 50 % infective dose in chicken embryos

Excipients (included in the solvent for ocular administration):

Patent blue V (E-131).....0.003 mg

Yellowish lyophilisate .

Solvent: Dark blue clear solution.

4. INDICATION(S)

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).

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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 $\geq 100 \mu\text{m}$) 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

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 freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.

Shelf life after dilution or reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate only healthy animals.

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 as 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.

Lay:

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

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.

Overdose (symptoms, emergency procedures, antidotes):

No symptoms other than those indicated in section “Adverse reactions” have been observed following administration of tenfold overdose.

Incompatibilities:

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

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

Medicines should not be disposed of via wastewater or household waste.

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

15. OTHER INFORMATION

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.