A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX FOR THE LYOPHILISATE}
10 x 500 ds
10 x 1,000 ds
10 x 2,500 ds
10 x 5,000 ds

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAVIAR-B1 lyophilisate for suspension for chickens.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.03 ml dose contains:
Live attenuated Newcastle Disease Virus, strain B1.....$10^{6.5}$ – $10^{7.7}$ EID_{50}*
* 50 % infective dose in chicken embryos

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension or for use in drinking water.

4. PACKAGE SIZE

10 x 500 doses
10 x 1,000 doses
10 x 2,500 doses
10 x 5,000 doses

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Disposal: read package leaflet.

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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX FOR THE SOLVENT}
10 x 1 bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAVIAR-B1 solvent

2. STATEMENT OF ACTIVE SUBSTANCES

Patent blue V (E-131)…….…….0.003 mg

3. PHARMACEUTICAL FORM

Solvent for suspension.

4. PACKAGE SIZE

10 x 32 ml

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oculonasal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Disposal: read package leaflet.

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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{LABELS FOR VIALS OF LYOPHILISATE}

500, 1,000, 2,500, 5,000 doses/glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAVIAR-B1 lyophilisate for suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 0.03 ml dose contains:
Live attenuated Newcastle Disease Virus, strain B1.....$10^{6.5}$ – $10^{7.7}$ EID_{50}*
* 50 % infective dose in chicken embryos

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

500 doses
1,000 doses
2,500 doses
5,000 doses

4. ROUTE(S) OF ADMINISTRATION

Oculonasal, drinking water and spray use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{LABELS FOR BOTTLES OF SOLVENT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAVIAR-B1
Solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Patent blue V (E-131)…….…….0.003 mg

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

32 ml for suspension of 1,000 doses

4. ROUTE(S) OF ADMINISTRATION

Oculonasal use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.