

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cryptisel 0.5 mg/ml oral solution for calves [AT, CY, CZ, DE, EL, ES, HU, IE, IT, LT, LV, NL, PL, PT, RO, SK, UK]

Cryptisel, 0.5 mg/ml oral solution for calves [EE]

Cryptisel vet 0.5 mg/ml oral solution for calves [DK, NO, SE]

Halofuginone

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Halofuginone 0.50 mg

Equivalent to 0.6086 mg of Halofuginone lactate

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

290 ml

490 ml

980 ml

5. TARGET SPECIES

Cattle (newborn calves).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Meat and offal: 13 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened use within 6 months

Use by ...

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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

Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat
(Barcelona) Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 290 ml, 490 ml or 980 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cryptisel 0.5 mg/ml oral solution for calves [AT, CY, CZ, DE, EL, ES, HU, IE, IT, LT, LV, NL, PL, PT, RO, SK, UK]

Cryptisel, 0.5 mg/ml oral solution for calves [EE]

Cryptisel vet 0.5 mg/ml oral solution for calves [DK, NO, SE]

Halofuginone

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Halofuginone 0.50 mg

Equivalent to 0.6086 mg of Halofuginone lactate

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

290 ml

490 ml

980 ml

5. TARGET SPECIES

Cattle (newborn calves).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Meat and offal: 13 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened use within 6 months.

Use by ...

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to protect from light.

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

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”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat
(Barcelona) Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch {number}