

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexrapid 2 mg/ml solution for injection
(AT, BE, BG, CZ, DE, EL, ES, FR, HU, IE, LT, NL, PL, PT, RO, SI, SK)

Dexrapid vet. 2 mg/ml solution for injection
(DK, FI)

Dexapid vet. 2 mg/ml solution for injection
(SE)

Dexamethasone

2. STATEMENT OF ACTIVE SUBSTANCES

Dexamethasone (as dexamethasone sodium phosphate) 2 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs and cats

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horses: intramuscular, intravenous, intraarticular

Cattle, pigs: intramuscular

Dogs, cats: intramuscular, intravenous

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Horses: Meat and offal: 8 days

Not authorised for use in mares producing milk for human consumption.

Cattle: Meat and offal: 8 days

Milk: 72 hours

Pigs: Meat and offal: 2 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Do not freeze.

Keep the vial in the outer carton in order to 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

Richter Pharma AG, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml colourless glass vial with a bromobutyl rubber stopper and an aluminium caps

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexrapid 2 mg/ml solution for injection
(AT, BE, BG, CZ, DE, EL, ES, FR, HU, IE, LT, NL, PL, PT, RO, SI, SK)

Dexrapid vet. 2 mg/ml solution for injection
(DK, FI)

Dexapid vet. 2 mg/ml solution for injection
(SE)

Dexamethasone

2. STATEMENT OF ACTIVE SUBSTANCES

Dexamethasone (as dexamethasone sodium phosphate) 2 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs and cats

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horses: intramuscular, intravenous, intraarticular

Cattle, pigs: intramuscular

Dogs and cats: intramuscular, intravenous

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Horses: Meat and offal: 8 days

Not authorised for use in mares producing milk for human consumption.

Cattle: Meat and offal: 8 days
Milk: 72 hours
Pigs: Meat and offal: 2 days

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days by

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

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

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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”

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Richter Pharma AG, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}