ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexa-ject 2 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Dexamethasone	2 mg/ml
as dexamethasone sodium phosphate	2.63 mg/ml

3. PACKAGE SIZE

50 ml
100 ml

4. TARGET SPECIES

Cattle, horses, pigs, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses: intravenous, intramuscular or intra-articular injection.
Cattle, pigs, dogs and cats: intramuscular injection.

7. WITHDRAWAL PERIODS

Withdrawal period:

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

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

Once opened, use by …

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 28365/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexa-ject 2 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Dexamethasone	2 mg/ml
as dexamethasone sodium phosphate	2.63 mg/ml

3. TARGET SPECIES

Cattle, horses, pigs, dogs and cats

4. ROUTES OF ADMINISTRATION

Horses: IV, IM or intra-articular injection.
Cattle, pigs, dogs and cats: IM injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

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

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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Once opened, use by …

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexa-ject

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Dexamethasone	2 mg/ml
as dexamethasone sodium phosphate	2.63 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Once opened, use by …

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dexa-ject 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats.

2. Composition

Each ml contains:

Active substance:

Dexamethasone	2 mg
as dexamethasone sodium phosphate	2.63 mg

Excipients:

Benzyl alcohol (E1519)	15 mg

Clear, colourless, aqueous solution for injection.

3. Target species

Cattle, horses, pigs, dogs and cats.

4. Indications for use

Horses, cattle, pigs, dogs and cats:
Treatment of inflammatory or allergic conditions.

Cattle:
Induction of parturition.
Treatment of primary ketosis (acetonaemia).

Horses:
Treatment of arthritis, bursitis or tenosynovitis.

5. Contraindications

Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, hyperadrenocorticism or osteoporosis.
Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections.
Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.
Do not administer intra-articularly where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
See also Special Warnings.

6. Special warnings

Special precautions for safe use in the target species:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.
Use of corticosteroids in horses has been reported to induce laminitis. Therefore horses treated with such preparations should be monitored frequently during the treatment period.
Because of the pharmacological properties of the active ingredient, special care should be taken when the product is used in animals with a weakened immune system.
Except in cases of acetonaemia and induction of parturition, the purpose of corticosteroid administration is to produce an improvement in clinical signs rather than a cure. The underlying disease should be further investigated. Following intra-articular administration, use of the joint should be minimized for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product contains dexamethasone, which can cause allergic reactions in some people.
People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.
Wash hands after handling the product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Pregnant women should not handle this veterinary medicinal product.

Pregnancy and lactation:
Apart from the use of the product to induce parturition in cattle, the use of corticosteroids is not recommended during pregnancy. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.
Use of the product in lactating cows may cause a reduction in milk yield.

Interaction with other medicinal products and other forms of interaction:
Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.
Because corticosteroids can reduce the immune response to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.
Concurrent use with anticholinesterase may lead to increased muscle weakness in patients with myasthenia gravis.
Glucocorticoids antagonise the effects of insulin.
Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethasone.

Overdose:
An overdose can induce drowsiness and lethargy in horses.

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

7. Adverse events

Cattle, horses, pigs, dogs and cats:

Undetermined frequency (cannot be estimated from the available data):	Iatrogenic hyperadrenocorticism (Cushing's disease)[1] Polyuria[2], polydipsia[2], polyphagia[2] Sodium retention[3], water retention[3], hypokalaemia[3] Cutaneous calcinosis Delayed wound healing, weakened resistance to or exacerbation of existing infections[4] Gastro-intestinal ulceration[5], hepatomegaly[6] Changes in blood biochemical and haematological parameters Hyperglycaemia[7] Retained placenta[8] Reduced viability of the calf[9] Pancreatitis[10] Milk production decrease Laminitis

[1] Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g., redistribution of body fat, muscle weakness and wastage and osteoporosis may result.
[2] After systemic administration and particularly during early stages of therapy.
[3] Upon long-term use.
[4] In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.
[5] May be exacerbated in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
[6] With increased serum hepatic enzymes.
[7] Transient.
[8] When used for induction of parturition in cattle, with possible subsequent metritis and/or subfertility.
[9] When used for induction of parturition in cattle particularly at early time points.
[10] Increased risk of acute pancreatitis.

Anti-inflammatory corticosteroids, such as dexamethasone, are known to exert a wide range of side effects. Whilst single high doses are generally well tolerated, they may induce severe side effects upon long-term use and when esters possessing a long duration of action are administered. During medium to long-term use, the dose should therefore generally be kept to the minimum necessary to control symptoms.

During therapy effective doses suppress the hypothalamic-pituitary-adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment (for further discussion see standard texts).

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Cattle, pigs, dogs and cats: intramuscular use.
Horses: intravenous, intramuscular or intraarticular use.

Treatment of inflammatory or allergic conditions:
Horses, cattle, pigs: 0.06 mg dexamethasone/kg body weight corresponding to 1.5 ml/50 kg
Dogs, cats: 0.1 mg dexamethasone/kg body weight corresponding to 0.5 ml/10 kg

The actual dose used should be determined by the severity of the signs and the length of time for which they have been present.

Treatment of primary ketosis in cattle (acetonaemia):
0.02 to 0.04 mg dexamethasone/kg body weight corresponding to a dose of 5-10 ml per 500 kg BW dependent on the size of the cow and the duration of the signs. Care should be taken not to overdose Channel Island breeds. Larger doses will be required if the signs have been present for some time or if relapsed animals are being treated.

Induction of parturition - to avoid foetal oversize and mammary oedema in cattle:
0.04 mg dexamethasone/kg body weight corresponding to 10 ml per 500 kg BW after day 260 of pregnancy.
Parturition will normally occur within 48-72 hours.

Treatment of arthritis, bursitis or tenosynovitis in horses:
1 - 5 ml of the veterinary medicinal product by intra-articular injection.
These quantities are not specific and are quoted purely as a guide. Injections into joint spaces or bursae should be preceded by the removal of an equivalent volume of synovial fluid. Strict asepsis is essential.

To ensure a correct dosage, body weight should be determined as accurately as possible.
To measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.
When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The maximum number of broachings should be limited to 50.

9. Advice on correct administration

See above.

10. Withdrawal periods

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

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

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 28365/3000

Cardboard box containing 1 vial of 50 or 100 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
Tel: +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for the batch release:
Dopharma B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer

17. Other information

Approved 22 September 2023