ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

100 ml vial and cartons of all three presentations

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rapidexon 2 mg/ml solution for injection
Dexamethasone sodium phosphate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg

Excipient:
Benzyl alcohol (E1519), 15.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

25/50/100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous, intramuscular, intra-articular, local or intrabursal injection
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle	meat and offal: 8 days
	milk: 72 hours
Pig	meat and offal: 2 days
Horse	meat and offal: 8 days

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

9. SPECIAL WARNING(S), IF NECESSARY

User warning: In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician.
People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.
Pregnant women should not handle this veterinary medicinal product.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 28 days.
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.
Keep vial in the outer carton.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

Eurovet Animal Health BV Handelsweg 25, 5531 AE Bladel, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

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17. MANUFACTURER'S BATCH NUMBER

Batch {number}

Vm 16849/4007

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

25 / 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rapidexon 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats
Dexamethasone sodium phosphate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains: Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg

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

25/50 ml

4. ROUTE(S) OF ADMINISTRATION

For intravenous, intramuscular, intra-articular, local or intrabursal injection

5. WITHDRAWAL PERIOD

Cattle meat and offal: 8 days
milk: 72 hours
Pig meat and offal: 2 days
Horse meat and offal: 8 days
Not authorised for use in horses producing milk for human consumption.

6. BATCH NUMBER

Batch{number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 28 days.
Once broached use by …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Vm 16849/4007

POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Rapidexon 2 mg/ml, solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Eurovet Animal Health BV Handelsweg 25, 5531 AE Bladel, The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rapidexon 2 mg/ml, solution for injection for horses, cattle, pigs, cats and dogs.
Dexamethasone sodium phosphate

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

1 ml contains:
Active substance:
Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 mg

Excipient:
Benzyl alcohol (E1519) 15.0 mg

A clear colourless solution practically free from particles.

4. INDICATION(S)

In horses, cattle, pigs, dogs and cats:
Treatment of inflammatory and allergic conditions

In cattle:
Treatment of primary ketosis
Induction of calving.

In horses:
Treatment of inflammation of joints, bursae, tendons or tendon sheaths

5. CONTRAINDICATIONS

Except in emergency situations, do not use in animals suffering from diabetes, kidney insufficiency, heart insufficiency, Cushing's disease or osteoporosis.
Do not use in viral infections during the viraemic stage or in cases of systemic fungal infections.
Do not use in animals suffering from gastrointestinal ulcers or ulcers of the cornea, or demodicosis.
Do not administer intra-articularly where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis (cell death).
Do not use in known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredient of the product.
Refer to Special warnings.

6. ADVERSE REACTIONS

Corticosteroids are known to exert a wide range of side effects. Whilst single high doses are generally well tolerated, they may induce severe adverse reactions with long term use and when esters

possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control clinical signs.
Steroids themselves, during treatment, may cause iatrogenic hyperadrenocorticism (Cushings disease) symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and wastage, and osteoporosis may result.
During therapy effective doses suppress the interaction between the hypothalamus, pituitary gland and adrenal gland cortex. Following cessation of treatment, signs 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 information see standard texts).
Systemically administered corticosteroids may cause polyuria (large volume of urine), polydipsia (thirst) and polyphagia (hunger), particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia (low potassium in the blood) in long term use. Systemic corticosteroids have caused deposition of calcium in the skin.
Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, concurrent antibacterial therapy is usually required. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs, and in animals with spinal cord trauma.
Corticosteroid use may cause enlargement of the liver with increased serum liver enzymes and may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include retained placenta, metritis, subfertility, laminitis, reduction in milk yield, changes in blood biochemical and haematological parameters.
Transient hyperglycaemia can occur.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses, cattle, pigs, cats and dogs.

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

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

For the treatment of inflammatory or allergic conditions the following average doses are advised. However, the actual dose used should be determined by the severity of the signs and the length of time for which they have been present.

Species	**Dosage**
Horses, cattle, pigs	0.06 mg/kg body weight corresponding to 1.5 ml/50 kg
Dog, cat	0.1 mg/kg body weight corresponding to 0.5 ml/10 kg

For the treatment of primary ketosis in cattle
0.02 to 0.04 mg/kg body weight corresponding to 5-10 ml per cow given by intramuscular injection is recommended 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.

For the induction of calving.
0.04 mg/kg body weight corresponding to 10 ml per cow as a single intramuscular injection after day 270 of pregnancy.
Calving will normally occur within 48-72 hours.

For the treatment of inflammation of joints, bursae, tendons or tendon sheaths by single intra-articular, intrabursal or local injection in the horse:

Dosage 1-5 ml

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.

9. ADVICE ON CORRECT ADMINISTRATION

To measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

10. WITHDRAWAL PERIOD

Cattle	meat and offal: 8 days
	milk: 72 hours
Pig	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. Do not freeze. Keep the vial in the outer carton.

Do not use this veterinary medicinal after the expiry date which is stated on the label and carton after EXP
The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days.
When the container is broached for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written on the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
If the veterinary medicinal product is used for induction of parturition in cattle, then a high incidence of retained placentae may be experienced and possible subsequent metritis and/or subfertility.
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.
When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper.
Except in cases of acetonemia and induction of the parturition, corticoid administration is used to induce an improvement in clinical signs rather than a cure.

Following intra-articular administration, use of the joint should be minimised for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.
Only the 25 ml vial should be used to treat cats, dogs and small piglets, to prevent excessive puncturing of the closure.

Special precautions to be taken by the person administering the veterinary medicinal product to animals: In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician.
People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.
Pregnant women should not handle this veterinary medicinal product.

Pregnancy, lactation:
Do not administer the product in pregnant females, except where the intention is to induce parturition.
Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals.
Administration in late pregnancy is likely to cause abortion or early calving in ruminants and may have a similar effect in other species.
Use of the veterinary medicinal product in lactating cows may cause a reduction in milk yield.

Interaction with other medicinal products and other forms of interaction:
In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.
Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.
Because corticosteroids can reduce the immunoresponse 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 heart 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 (symptoms, emergency procedures, antidotes):
An overdose can induce drowsiness and lethargy in horses. Refer to Adverse reactions.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2014

15. OTHER INFORMATION

25/50/100 ml
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom