ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMECINE 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats
Dexamethasone

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:

Dexamethasone	2 mg
As dexamethasone sodium phosphate	2.63 mg

Excipients:

Benzyl alcohol (E 1519)	15.6 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1x100 ml

5. TARGET SPECIES

Cattle, horses, pigs, dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use. - *already mentioned in point 7*
Pregnant women should not handle this product.

10. EXPIRY DATE

EXP
Shelf life after first opening the immediate packaging: 28 days.
Once opened use by ……..

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material 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

Vet-Agro Trading Sp. Z o.o.
Melgiewska str. 18
20-234 Lublin
Poland

16. MARKETING AUTHORISATION NUMBER

Vm 41715/4005

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMECINE 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats
Dexamethasone

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:

Dexamethasone	2 mg
As dexamethasone sodium phosphate	2.63 mg

Excipients:

Benzyl alcohol (E 1519)	15.6 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, horses, pigs, dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use – *already mentioned in point 7*
Pregnant women should not handle this product.

10. EXPIRY DATE

EXP
Shelf life after first opening the immediate packaging: 28 days.
Once opened use by ……..

11. SPECIAL STORAGE CONDITIONS

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

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

Vet-Agro Trading Sp. Z o.o.
Melgiewska str. 18
20-234 Lublin
Poland

16. MARKETING AUTHORISATION NUMBER

Vm 41715/4005

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

DEXAMECINE 2 mg/ml solution for injections for cattle, horses, pigs, dogs and cats

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

Marketing authorisation holder:
Vet-Agro Trading Sp. Z o.o.
Melgiewska str. 18
20-234 Lublin
Poland

Manufacturer responsible for batch release:
Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32, 20-616 Lublin, Poland
Tel.+48 81 445 23 00
Fax. +48 81 44 52 320
E-mail vet-agro@vet-agro.pl

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMECINE 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats
Dexamethasone

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

Each ml contains:
Active substance:

Dexamethasone	2 mg
As dexamethasone sodium phosphate	2.63 mg

Excipients:

Benzyl alcohol (E 1519)	15.6 mg

Clear, colourless aqueous solution

4. INDICATION(S)

Horses
Treatment of inflammation and allergic reactions.
Treatment of arthritis, bursitis or tenosynovitis.

Cattle
Treatment of inflammation and allergic reactions.
Induction of parturition.
Treatment of primary ketosis (acetonaemia).

Pigs
Treatment of inflammation and allergic reactions.

Dogs and cats
Treatment of inflammation and allergic reactions.

5. CONTRAINDICATIONS

Except in emergency situations the product should not be used in animals suffering from diabetes, chronic nephritis, renal disease, congestive heart failure and osteoporosis.
For infectious diseases it is necessary that application of corticosteroids is associated with effective antibiotic or chemotherapeutic treatment.
Use of the product is contraindicated in immunodeficient animals, as well as in case of septic process, mycoses or parasitoses.
Do not use in animals affected by gastrointestinal or corneal ulcers, or demodecosis.
Do not use in case of aseptic bone necrosis, poor healing wounds or fractures.
Do not use in animals affected with Cushing's syndrome.
Do not use in animals suffering from cataract or glaucoma.
Do not use in pancreatitis, hypertonia, hypocalcaemia.
Do not use the veterinary medicinal product in the course of active vaccination.
Do not use in cases of known hypersensitivity to active substance or to any of the excipients.

6. ADVERSE REACTIONS

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 in 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 symptoms.
Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result. Steroids may cause diabetogenic effects combined with reduced glucose tolerance, steroid induced or deterioration of existing diabetes mellitus.

Systematically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).
Steroids may increase risk of thrombosis.
Administration of steroids leads to ACTH suppression and reversible inactivity atrophy of the suprarenal gland.
Lowering of convulsive threshold, possible manifestation of latent epilepsy, euphoric effects, excitation were observed after administration of corticosteroids.
Administration of corticosteroids may cause atrophy of the skin.
Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections and may delayed bone healing and arthropathy.

Gastro-intestinal ulceration has been reported in animals treated with corticosteroids and g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
Hypersensitivity reactions are possible, though rare.
If the 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.
Corticosteroid use may increase the risk of acute pancreatitis.
Steroids may be related to behavioral changed in dogs and cats (occasional depression in cats and dogs, aggressiveness in dogs).
Other adverse reactions, such as hypertonia, edema, hypocalcemia, growth retardation with disruptive bone growth and damage of bone matrix and ophthalmic disorders (glaucoma, cataract) may be observed after administration of steroids.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, horses, pigs, dogs and cats

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

Horses
Intramuscular or intraarticular administration.

Cattle, pigs, dogs and cats
Intramuscular administration.

For the treatment of inflammatory or allergic conditions the following doses administered as single intramuscular injection are advised:

Species	**Dosage (i.m.)**
Horses, cattle, pigs	0.06 mg of dexamethasone/kg bw (1.5 ml of product/50 kg bw)
Dog, cat	0.1 mg of dexamethasone/ kg bw (0.5 ml of product/10 kg bw)

For the treatment of primary ketosis in cattle a dose of 0.02-0.04 mg of dexamethasone/kg bw (5-10 ml of product per animal) given by single intramuscular injection is advocated 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 (i.e. 0.04 mg/kg) will be required if the signs have been present for some time or if relapsed animals are being treated.

For the induction of parturition - to avoid foetal oversize and mammary oedema in cattle.
A single intramuscular injection of 10 ml of product after day 260 of pregnancy. Parturition will normally occur within 48-72 hours.

For the treatment of arthritis, bursitis or tenosynovitis by intra-articular injection in the horse.
Dose 1 - 5 ml of product *pro toto*

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.

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

The cap should not be punctured more than 125 times. When treating groups of animals in one run, it is recommended to use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 8 days
Milk: 72 hours
Pigs:
Meat and offal: 2 days
Horses:
Meat and offal: 8 days
Not authorized for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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 label after EXP.
Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None

Special precautions for use in animals:
The induction of parturition with corticosteroids may be associated with reduced viability of calves, an increased incidence of retained placentae and possible subsequent metritis and/or subfertility in cattle.
Care should be taken when the product is used for the treatment of laminitis in horses, where there is the possibility that such treatment could worsen the condition. The use of the product in horses for other conditions could induce laminitis and careful observation during the treatment period should be made.

During therapy effective doses suppress the hypothalamo-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, e.g. dosing to coincide with the time of the endogenous cortisol peak (i.e. in the morning with regard to dogs and the evening regarding cats) and a gradual reduction of dosage.

Its use in younger or older individuals may be associated with an increased risk of side effects. Therefore, it is necessary to decrease the dose and clinical monitoring during treatment. During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used.
In the presence of infections, steroids may worsen or hasten the progress of the disease.

Except in cases of ketosis and induction of parturition, corticosteroid administration is to induce an improvement in clinical signs rather than a cure. The underlying disease should be further investigated.
Due to their immunosuppressive activity, corticosteroids can lead to a reduced response to vaccination. Therefore, it is recommended that product should not be used in combination with vaccines.
In suckling animals, the veterinary medicinal product should be used only according to the benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection as dexamethasone can cause allergic reactions in some people.
People with known hypersensitivity to the dexamethasone should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Dexamethasone may affect fertility or the unborn child. To avoid the risk from accidental self-injection, pregnant women should not handle this product.
This product is a skin and eye irritant. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/irrigate the area with clean running water. Seek medical attention if irritation persists.
Wash hands after use.

Pregnancy:
Apart from the use of veterinary medicinal product to induce parturition in cattle, corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused fetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion. If the 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.

Lactation:
Use of the corticosteroids in lactating cows may cause a temporary reduction in milk yield.

Interaction with other medicinal products and other forms of interaction:
Because corticosteroids can reduce the immune response to vaccination, the product should not be used in combination with vaccines.
Dexamethasone should not be administered in conjunction with other anti-inflammatory substances since it increases the risk for gastric ulcers or intestinal bleeding.
Product administration may cause hypokalaemia thus increasing the risk of toxicity of cardiac glycosides.
The risk of hypokalemia can increase when dexamethasone is administered in conjunction with diuretics which influence on excretion of potassium.
Co-administration with cholinesterase inhibitors can lead to muscle weakness in patients suffering from myasthenia gravis.
Glucocorticoids antagonize insulin.
Co-administration of phenobarbital, phenytoin and rifampicin can suppress the effect of dexamethasone.
Increased intraocular pressure may occur when anticholinergic drugs such as atropine are administered simultaneously with dexamethasone.
Dexamethasone reduces effect of anticoagulants.

Overdose (symptoms, emergency procedures, antidotes):
High doses of corticosteroids may cause apathy and lethargy in the horses. High doses may cause thrombosis due to a higher tendency to blood clotting. Continuous overdosing may result in development of Cushing syndrome. See point 6 (adverse reactions).

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

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

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package size: cardboard box containing 100 ml bottle

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 28 July 2022