ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 1 bottle of 50ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trovex 1 mg/ml suspension for injection for cattle, horses, pigs, cats and dogs.
Dexamethasone isonicotinate.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Dexamethasone isonicotinate 1.00 mg (equivalent to 0.79 mg dexamethasone)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50ml

5. TARGET SPECIES

Cattle, horses, pigs, cats and dog

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horse, cattle, pigs: intramuscular
Cats, dogs: intramuscular, subcutaneous
Shake well before use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle:
Meat and offal: 55 days
Milk: 60 hours
Pigs:
Meat and offal: 55 days
Horses:
Meat and offal: 63 days
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening of the immediate packaging: 28 days
Once broached, use by: ... ...

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Store in the original container.
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.

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

Emdoka bvba
John Lijsentraat 16
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 34534/4008

17. MANUFACTURER'S BATCH NUMBER

<Batch>
<Lot>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 50ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trovex 1 mg/ml suspension for injection for cattle, horses, pigs, cats and dogs.
Dexamethasone isonicotinate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains: Dexamethasone isonicotinate 1.00 mg (equivalent to 0.79 mg dexamethasone)

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

50ml

4. ROUTE(S) OF ADMINISTRATION

Horse, cattle, pigs: IM
Cats, dogs: IM, SC
Shake well before use. Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle:
Meat and offal: 55 days
Milk: 60 hours
Pigs:
Meat and offal: 55 days
Horses:
Meat and offal: 63 days
Not authorised for use in horses producing milk for human consumption.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

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

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Trovex 1 mg/ml suspension for injection for cattle, horses, pigs, cats and dogs.

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

Marketing authorisation holder:
Emdoka bv
John Lijsenstraat 16,
2321 Hoogstraten,
Belgium

Manufacturer responsible for batch release:
Divasa Farmavic S.A.
Ctra. Sant Hipolit, Km. 71
Gurb Vic, 08503, Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trovex 1 mg/ml suspension for injection for cattle, horses, pigs, cats and dogs.
Dexamethasone isonicotinate

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

Each ml contains:
Active substances:
Dexamethasone isonicotinate 1.00mg
(equivalent to 0.79 mg dexamethasone)
Excipients:
Methyl parahydroxybenzoate (E218) 1.35mg
Propyl parahydroxybenzoate 0.15mg

Suspension for injection
White to yellowish white suspension

4. INDICATION(S)

Horses, cattle, pigs, dogs and cats:
Treatment of inflammatory skin conditions, diseases of the locomotor system and diseases of the respiratory system.
Cattle:
Treatment of ketosis (acetonaemia).

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 use in animals with known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredient of the product.
See also section 12.Do not use for the treatment of laminitis in horses, where there is the possibility that such treatment could worsen the condition.

6. ADVERSE REACTIONS

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 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, during treatment, may cause iatrogenic hyperadrenocorticism (Cushing's disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result. 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.
Systemically 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) and may cause atrophy of the skin.

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, anti-bacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of 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 corticosteroid-treated animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
Steroids may be related to behavioural changes in dogs and cats (occasional depression in cats and dogs, aggressiveness in dogs).
Corticosteroid use may induce changes in blood biochemical and haematological parameters. Transient hyperglycaemia can occur.
Corticosteroid use may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include laminitis and reduction in milk yield.
In very rare cases anaphylactic reactions can occur. These reactions may be fatal.

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, cats and dogs

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

Horses, cattle and pigs
Intramuscular administration.
Cattle, calves, horses and foals: 0.02 mg of dexamethasone isonicotinate /kg body weight (equivalent to 0.016 mg of dexamethasone/kg) corresponding to 2ml/100 kg bodyweight
Pigs: 0.02 mg of dexamethasone isonicotinate /kg body weight (equivalent to 0.016 mg of dexamethasone/kg) corresponding to 2 ml/100 kg bodyweight
Piglets: 0.1 mg of dexamethasone isonicotinate /kg body weight (equivalent to 0.08 mg of dexamethasone/kg) corresponding to 1 ml/10 kg bodyweight
The maximal volume to be administered per injection site is 10ml in cattle and horses and 3ml in pigs.

Dogs and cats
Intramuscular or subcutaneous administration.
Dogs and cats: 0.1 mg of dexamethasone isonicotinate /kg body weight (equivalent to 0.08 mg of dexamethasone/kg) corresponding to 1 ml/10 kg bodyweight

The therapeutic effect of the product lasts for approximately 4 days. In horses, cats and dogs, where longer term treatment is necessary, an appropriate corticosteroid preparation should be used.

Shake well before use. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

Do not broach the vial more than 25 times.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 55 days
Milk: 60 hours
Pigs:
Meat and offal: 55 days
Horses:
Meat and offal: 63 days
Not authorised for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Store in the original container.
Keep the vial in the outer carton in order to protect from light.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

During a course of treatment the situation should be reviewed frequently by close veterinary supervision.
Care should be taken not to overdose Channel Island breeds.
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 ketosis corticosteroid administration is to induce an improvement in clinical signs rather than a cure.
The underlying disease should be further investigated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This product contains dexamethasone and parahydroxybenzoates (parabens), which can cause allergic reactions in some people.
People with known hypersensitivity to dexamethasone or to any of the excipients 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. Pregnant women should not handle this veterinary medicinal 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 and lactation:

Corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.

Interaction with other medicinal products and other forms of interaction:

Gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs.
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.
Amphotericin B administered concomitantly with glucocorticoids may cause hypokalemia.
Glucocorticoids may also inhibit the hepatic metabolism of cyclophosphamide; dosage adjustments may be required.
Concomitant administration of glucocorticoids and cyclosporine may increase the blood levels of each, by mutually inhibiting the hepatic metabolism of each other; the clinical significance of this interaction is not clear.
Dexamethasone may decrease diazepam levels.
Ephedrine may reduce dexamethasone blood levels and interfere with dexamethasone suppression tests.
Ketoconazole and other azole antifungals may decrease the metabolism of glucocorticoids and increase dexamethasone blood levels; ketoconazole may induce adrenal insufficiency when glucocorticoids are withdrawn by inhibiting adrenal corticosteroid synthesis.
Macrolide antibiotics (erythromycin, clarithromycin) may decrease the metabolism of glucocorticoids and increase dexamethasone blood levels.
Mitotane may alter the metabolism of steroids; higher than usual doses of steroids may be necessary to treat mitotane-induced adrenal insufficiency.

Overdose (symptoms, emergency procedures, antidotes):
An overdose can induce drowsiness and lethargy in horses. See also section 6.

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

Cardboard box containing 1 vial of 50 ml
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 09 November 2021