SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Dexamethasone isonicotinate 1.00 mg
(equivalent to 0.79 mg dexamethasone)

Excipients:
Methyl parahydroxybenzoate (E218) 1.35 mg
Propyl parahydroxybenzoate 0.15 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
White to yellowish white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, pigs, cats and dogs

4.2 Indications for use, specifying the target species

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).

4.3 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 4.7.
Do not use for the treatment of laminitis in horses, where there is the possibility that such treatment could worsen the condition.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 of cattle.
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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

Dexamethasone should not be given together with other anti-inflammatory substances. 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.
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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

An overdose can induce drowsiness and lethargy in horses. See also section 4.6.

4.11 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.

5. PHARMACOLOGICAL OR IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use, plain, glucocorticoids
ATCvet Code: QH02AB02

5.1 Pharmacodynamic properties

Dexamethasone is a potent synthetic glucocorticoid with low mineralocorticoid activity. Corticosteroids may decrease the immune response. Indeed, they inhibit capillary dilatation, leukocyte migration and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis. Compared with base dexamethasone, the product has three times the glucogenic effect and seven times the anti-inflammatory effect, and comparatively little effect on milk yield when used in lactating cows.

5.2 Pharmacokinetic particulars

The product contains a potent long acting corticosteroid with a therapeutic effect lasting for approximately 4 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Sodium Chloride
Polysorbate 80 (E433)
Water for Injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not refrigerate or freeze.
Store in the original container.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

One amber, glass (Ph. Eur. Type I or Ph. Eur. siliconized Type II) multidose vial containing 50 ml of product, sealed with a grey siliconized bromobutyl rubber stopper and aluminium cap, in a cardboard box

Pack sizes:
Cardboard box containing 1 vial of 50 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Emdoka bvba
John Lijsentraat 16
B-2321 Hoogstraten
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 34534/4008

9. DATE OF FIRST AUTHORISATION

09 November 2021

10. DATE OF REVISION OF THE TEXT

November 2021

Approved 09 November 2021