1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXASHOT 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Dexamethasone 2 mg
(equivalent to dexamethasone sodium phosphate 2.63 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E 1519)	15.6 mg
Sodium chloride	
Sodium citrate	
Citric acid monohydrate (for pH adjustment)	
Sodium hydroxide (for pH adjustment)	
Water for injections	

Clear, colourless solution

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs, dogs and cats.

3.2 Indications for use for each target species

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.

3.3 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 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, to corticosteroids and to any of the excipients.
See also section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Care should be taken not to overdose Channel Island breeds of cattle.
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 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.
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.

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 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, horses, pigs, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions
Undetermined frequency	Hyperadrenocorticism (Cushings disease)[1], adrenal gland disorders[2]

(cannot be estimated from the available data)	Electrolyte disorder (hypernatremia, hypokalaemia, water retention)[3], elevated liver enzymes, hyperglycaemia[4], other abnormal test result (changes in blood biochemical and haematological parameters) Cutaneous calcinosis, skin atrophy[5] Polydipsia[6], polyphagia[6], delayed healing Polyuria[6] Other immune system disorder[7] Gastrointestinal ulceration[8], acute pancreatitis Hepatomegaly Laminitis Milk production decrease Retained placenta (with possible subsequent metritis, subfertility)[9,10] Reduced viability of the calf [9,11] Abnormal behaviour (depression[12,13], aggression[12])

[1] Iatrogenic. Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis.
[2] 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.
[3] In long term use.
[4] It can occur transiently.
[5] It may be caused by systemic corticoteroids.
[6] When systemically administered corticosteroids and particularly during the early stages of therapy.
[7] Immunosuppressant actions may weaken resistance to or exacerbate existing infections. 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.
[8] It may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
[9] In cattle.
[10] The high incidence of this adverse event may be experienced if the product is used for induction of parturition.
[11] When used for induction of parturition particularly at early time points.
[12] In dogs.
[13] In cats.

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Apart from the use of the product to induce parturition in cattle, 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.
Use of the product in lactating cows may lead to reduction in milk secretion.
In suckling animals, the veterinary medicinal product should be used only according to the benefit-risk assessment by the responsible veterinarian.
See also section 3.6

3.8 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.

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.

3.9 Administration routes and dosage

Horses
Intramuscular, intravenous or intraarticular injection.
Cattle, pigs, dogs and cats
Intramuscular injection.

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

Species	**Dosage**
Horses, cattle, pigs	0.06 mg of dexamethasone /kg body weight corresponding to 1.5 ml of product/ 50 kg BW

Dogs, cats	0.1 mg of dexamethasone /kg body weight corresponding to 0.5 ml of product /10 kg BW

For the treatment of primary ketosis in cattle (acetonaemia) 0.02-0.04 mg of dexamethasone /kg body weight corresponding to a dose 5-10 ml of product per 500 kg BW given by single intramuscular injection is advocated dependent on the size of the cow and the duration of the signs. 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 0.04 mg of dexamethasone /kg body weight corresponding to 10 ml of product per 500 kg BW 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.
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. In horses producing food intended for human consumption a total dose of 0.06 mg dexamethasone/kg bw should not be exceeded.

The cap should not be punctured more than 100 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

An overdose can induce drowsiness and lethargy in horses.
See also section 3.6

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB02

4.2 Pharmacodynamics

Dexamethasone is a potent synthetic glucocorticoid with low mineralocorticoid activity.
Dexamethasone has ten to twenty times the anti-inflammatory activity of prednisolone at an equivalent molar dose. Corticosteroids may decrease the immune response. Indeed, they inhibit capillary

dilatation, leukocyte migration and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis. Administration of dexamethasone mimics the effects of cortisol and therefore produces a signal that initiates the induction of parturition in ruminants if the fetus is alive.

4.3 Pharmacokinetics

After administration of the product intramuscularly, dexamethasone sodium phosphate is rapidly absorbed and hydrolysed to dexamethasone (base) giving a rapid and short-acting response (approximately 48 hours). Tmax in cattle, goats, horses, swine, dogs and cats is reached within 30 minutes after intramuscular administration. T½ (half-life time) varies between 5 and 20 hours depending on the species. The bioavailability after intramuscular administration is approximately 100%.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 33 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

100 ml amber co-ex plastic (polypropylene) vials closed with brombutyl rubber stoppers and aluminium caps.

Pack size:
One vial of 100 ml in cardboard box.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vet-Agro Multi-Trade Company Sp. z o.o.

7. MARKETING AUTHORISATION NUMBER(S)

VPA20742/003/001

8. DATE OF FIRST AUTHORISATION

21/06/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

04/04/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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