B. PACKAGE LEAFLET

PACKAGE LEAFLET:

DEXASHOT 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 and 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

DEXASHOT 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)

Solution for injection.
Clear, colourless aqueous solution

Each 1 ml contains:
Active substance:

Dexamethasone	2 mg
As dexamethasone sodium phosphate	2.63 mg

Excipients:

Benzyl alcohol (E 1519)	15.6 mg

4. INDICATION(S)

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

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 administer intra-articularly where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis.
Do not use in known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredient of the product.
See also section SPECIAL WARNING(S) Pregnancy, Lactation.

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 sideeffects upon longterm 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.

Steroids themselves, during treatment, may cause iatrogenic hyperadrenocorticism (Cushing's disease)s 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 be related to behavioural changes in dogs and cats (occasional depression in cats and dogs, aggressiveness in dogs).

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 (for further discussion see standard texts).

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 upon 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, 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.

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.
Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
Corticosteroid use may induce changes in blood biochemical and haematological parameters.
Transient hyperglycaemia can occur.
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. Such use of dexamethasone, particularly at early time points, may be associated with reduced viability of the calf.
Corticosteroid use may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include laminitis and reduction in milk yield.

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, intravenous or intraarticular administration.

Cattle, pigs, dogs and cats
Intramuscular administration.

The product may be administered by intravenous or intramuscular injection in horses, and by intramuscular injection in cattle, pigs, dogs and cats. The product may also be given by intra-articular injection in horses. 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
Dog, cat	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.

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.

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 authorised 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:
Care should be taken not to overdose Channel Island breeds.
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.

Pregnancy:
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.

Lactation:
Use of the product in lactating cows may cause a reduction in milk yield.
See also section ADVERSE REACTIONS.

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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater of household waste.
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 vials

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