ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND THE IMMEDIATE PACKAGE

Outer carton + 100 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucadex 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats
dexamethasone (as sodium phosphate).

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Dexamethasone	2 mg
(as dexamethasone sodium phosphate	2.63 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horses: intravenous, intramuscular, intraarticular and intrabursal use.
Dogs and cats: intramuscular use
Cattle and pigs: intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

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.

9. SPECIAL WARNING(S), IF NECESSARY

Pregnant women should not handle this product. Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC 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. 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

MARKETING AUTHORISATION HOLDER:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

DISTRIBUTOR IN THE UK:
Anupco Ltd T/A Kela Animal Health UK
Office 39, Lodge House Lodge Park, Lodge Lane,
Langham, Colchester, Essex, CO4, 5NE
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 36408/5008

17. MANUFACTURER'S BATCH NUMBER

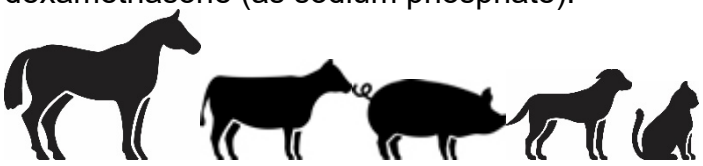
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucadex 2 mg/ml solution for injection
dexamethasone (as sodium phosphate).



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

2 mg/ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Horses: IV, IM, IA and intrabursal.
Dogs and cats: IM
Cattle and pigs: IM

5. WITHDRAWAL PERIOD

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.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Glucadex 2 mg/ml solution for injection for horses, cattle, 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:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Or

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucadex 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats
dexamethasone (as sodium phosphate)

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

1 ml contains:

Active substance:

Dexamethasone	2.0 mg
(as dexamethasone sodium phosphate)	2.63 mg

Excipients:

Benzyl alcohol (E1519)	15.6 mg

Solution for injection
Clear, colourless to slightly brownish aqueous solution.

4. INDICATION(S)

Horses, cattle, pigs, dogs and cats:
Treatment of inflammation and allergic reactions.

Horses:
Treatment of arthritis, bursitis or tenosynovitis.

Cattle:
Treatment of primary ketosis (Acetonemia).
Induction of parturition.

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 cases of known hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
See also the section on use during pregnancy and 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 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 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 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 infections, steroids may worsen or hasten the progress of the disease.

Gastro-intestinal ulceration has been reported in animals treated with corticosteroids and gastro-intestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs (NSAIDs)and in animals with spinal cord trauma.
Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Steroids may be associated with 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.

The induction of parturition with corticosteroids may be associated with reduced viability of calves, an increased incidence of retained placenta and possible subsequent metritis and/or subfertility in cattle.

Corticosteroid use may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include laminitis and reduction in milk yield.

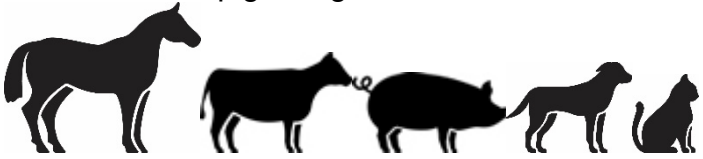
In very rare cases, hypersensitivity reactions may occur.

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

Horses, cattle, pigs, dogs and cats.



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

Horses
Intravenous, intramuscular, intraarticular and intrabursal use.

Cattle, pigs, dogs and cats
Intramuscular use.

For the treatment of inflammatory or allergic conditions the following average doses are advised. However, the actual dose used should be determined by the severity of the signs and the length of time for which they have been present.

Species	**Dosage**
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 (cattle: 5-10 ml of product per 500 kg bw) given by single intramuscular injection is advocated dependent on the size of the animal and the duration of the signs. Higher 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 in cattle - to avoid foetal oversize and mammary oedema. A single intramuscular injection of 0.04 mg of dexamethasone/kg bw (corresponding to 10 ml of product for a cow weighing 500 kg) after day 260 of pregnancy.
Parturition will normally occur within 48-72 hours.
For the treatment of arthritis, bursitis or tenosynovitis by a single intra-articular, intrabursal or local injection in the horse.
Dose 1 - 5 ml of product per treatment

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. In horses producing food intended for human consumption a total dose of 0.06 mg dexamethasone/kg bw should not be exceeded. Strict asepsis is essential.

9. ADVICE ON CORRECT ADMINISTRATION

10. 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.

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 carton and label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals:
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, the purpose of 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 minimized for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.
Care should be taken not to overdose Channel Island breeds of cattle.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product contains dexamethasone which can cause allergic reactions in some people. People with known hypersensitivity to dexamethasone should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental self-injection. 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 and Lactation:
Apart from the use of the 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 foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion. Use of corticosteroids in lactating cows may cause a temporary reduction in milk yield.
In suckling animals, the veterinary medicinal product should be used only according to the benefit-risk assessment by the responsible veterinarian.
See also the section on adverse reactions.

Interaction with other medicinal products and other forms of interaction:
Concurrent use with non-steroidal anti-inflammatory drugs (NSAIDs) 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.
Overdose (symptoms, emergency procedures, antidotes):
An overdose can induce drowsiness and lethargy in horses. See the section on 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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2023

15. OTHER INFORMATION

Pack sizes: 50 ml and 100 ml.

Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Vm 36408/5008

Distributed by:
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Langham, Colchester, Essex, CO4, 5NE
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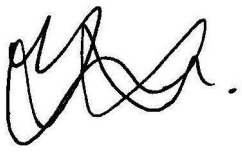

Approved: 19 September 2023