

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Glucadex 2 mg/ml solution for injection

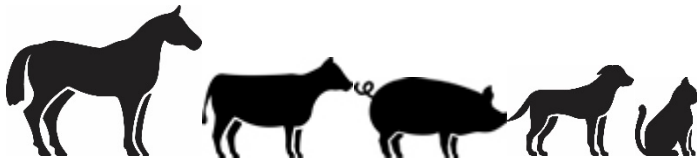
**2. STATEMENT OF ACTIVE SUBSTANCES**

Dexamethasone 2 mg/ml  
(as dexamethasone sodium phosphate 2.63 mg/ml)

**3. PACKAGE SIZE**

50 ml  
100 ml

**4. TARGET SPECIES**



**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Horses: IV, IM, IA and IB.  
Cattle, pigs, dogs and cats: IM.

**7. 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.

**8. EXPIRY DATE**

Exp. {mm/yyyy}  
Shelf life after first opening the container: 28 days.  
Once broached, use by...

## **9. SPECIAL STORAGE PRECAUTIONS**

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

## **10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

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

## **11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only. To be supplied only on veterinary prescription.

## **12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

## **13. NAME OF THE MARKETING AUTHORISATION HOLDER**

MARKETING AUTHORISATION HOLDER:  
Alfasan Nederland B.V.

DISTRIBUTOR IN THE UK:  
Anupco Ltd T/A Kela Animal Health UK

## **14. MARKETING AUTHORISATION NUMBER**

Vm 36408/5008

## **15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Glass vial of 100 mL}**

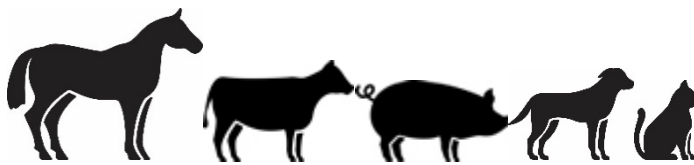
**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Glucadex 2 mg/ml solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Dexamethasone 2 mg/ml  
(as dexamethasone sodium phosphate 2.63 mg/ml)

**3. TARGET SPECIES**



**4. ROUTES OF ADMINISTRATION**

Horses: IV, IM, IA and IB.  
Cattle, pigs, dogs and cats: IM.

**5. 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.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf life after first opening the container: 28 days.

Once broached, use by...

**7. SPECIAL STORAGE PRECAUTIONS**

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

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

MARKETING AUTHORISATION HOLDER:

Alfasan Nederland B.V.

DISTRIBUTOR IN THE UK:  
Anupco Ltd T/A Kela Animal Health UK

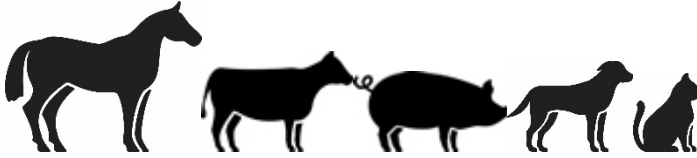
## **9. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS {Glass vial of 50 mL}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Glucadex



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Dexamethasone 2 mg/ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached, use within 28 days.

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

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

**2. Composition**

Each ml contains:

**Active substance:**

Dexamethasone	2.0 mg
(as dexamethasone sodium phosphate)	2.63 mg

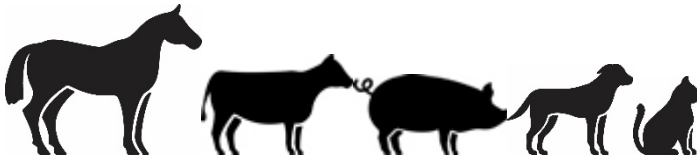
**Excipients:**

Benzyl alcohol (E1519)	15.6 mg
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Clear, colourless to slightly brownish aqueous solution.

**3. Target species**

Horses, cattle, pigs, dogs and cats.



**4. Indications for use**

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. Special warnings**

### Special precautions for safe use in the target species:

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 veterinary medicinal 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 veterinary medicinal 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, the veterinary medicinal product should not be administered by pregnant women.

This veterinary medicinal product is a skin and eye irritant. Avoid skin and eye contact. In the case of accidental contact of the product with the skin or eyes, wash/irrigate 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.

Use in suckling animals only according to the benefit-risk assessment by the responsible veterinarian. See also the section on adverse events.

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:

An overdose can induce drowsiness and lethargy in horses. See the section on Adverse events.

Major incompatibilities:

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

**7. Adverse events**

Horses, cattle, pigs, dogs and cats:

Very common (>1 animal / 10 animals treated):	Hypersensitivity reactions
Undetermined frequency	Iatrogenic hyperadrenocorticism (Cushing's disease) <sup>1</sup> , polyuria <sup>2</sup> , polydipsia <sup>2</sup> , polyphagia <sup>2</sup> , sodium retention <sup>3</sup> , water retention <sup>3</sup> , hypokalaemia <sup>3</sup> , cutaneous calcinosis, organ atrophy (skin), delayed wound healing, weakened resistance to or exacerbation of existing infections <sup>4</sup> , gastrointestinal ulceration <sup>5</sup> , hepatomegaly <sup>6</sup> , abnormal behaviour <sup>7</sup> , changes in blood biochemical and haematological parameters, hyperglycaemia (transient), reduced viability of the calf <sup>8</sup> , retained placenta <sup>9</sup> , acute pancreatitis <sup>10</sup> , laminitis, milk production decrease.

<sup>1</sup> Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result.

<sup>2</sup> After systemic administration and particularly during the early stages of therapy.

<sup>3</sup> Upon long-term use.

<sup>4</sup> 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.

<sup>5</sup> May be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs (NSAIDs) and in animals with spinal cord trauma.

<sup>6</sup> Increased serum hepatic enzymes.

<sup>7</sup> Occasional depression in cats and dogs, and aggressiveness in dogs.

<sup>8</sup> When the product is used for induction for parturition in cattle.

<sup>9</sup> Increased incidence and possible subsequent metritis and/or subfertility when the product is used for induction for parturition in cattle.

<sup>10</sup> Increased risk.

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.

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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## **8. Dosage for each species, routes 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.

<b>Species</b>	<b>Dosage</b>
Horses, cattle, pigs	0.06 mg of dexamethasone/kg body weight (1.5 ml of product/50 kg body weight)
Dog, cat	0.1 mg of dexamethasone/ kg body weight (0.5 ml of product/10 kg body weight)

#### For the treatment of primary ketosis in cattle

A dose of 0.02-0.04 mg of dexamethasone/kg body weight (cattle: 5-10 ml of product per 500 kg body weight) 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 - 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 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 body weight should not be exceeded. Strict asepsis is essential.

### **9. Advice on correct administration**

Not applicable.

### **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.

Shelf life after first opening the container: 28 days.

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.

### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

To administer only by a veterinarian or under their supervision.

### **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 36408/5008

50 ml and 100 ml clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a cardboard box.

Cardboard box with 1 vial of 50 ml

Cardboard box with 1 vial of 100 ml

Not all pack sizes may be marketed.

### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release:

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

Local representatives and contact details to report suspected adverse reactions:

Anupco Ltd T/A Kela Animal Health UK  
Office 39, Lodge House Lodge Park, Lodge Lane,  
Langham, Colchester, Essex, CO4, 5NE  
United Kingdom  
+44 1206 233528  
sales@kela.health

**17. Other information**

POM-V

*Gavin Hall*  
Approved: 10 June 2025