1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PREGLUKORD 25 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
25 mg prednisolone

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Starch, pregelatinised
Sodium starch glycolate (Type A)
Glycerol dibehenate
Magnesium stearate

9mm round flat uncoated white tablets with score line and marking 'A650' on one side and marking '25' on the other side.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For the symptomatic treatment or as adjunct treatment of inflammatory and immune-mediated diseases in dogs.

3.3 Contraindications

Do not use in animals with:
- Viral, mycotic or parasitic infections that are not controlled with an appropriate treatment
- Diabetes mellitus
- Hyperadrenocorticism
- Osteoporosis
- Heart failure
- Renal insufficiency
- Corneal ulceration
- Gastro-intestinal ulceration
- Glaucoma

Do not use in cases of hypersensitivity to the active substance, to other corticosteroids, or to any of the excipients.
See also sections 3.7 and 3.8.

3.4 Special warnings

Glucocorticoids can produce symptomatic improvements without treating the underlying disease. Where appropriate, use of the product should be combined with treatment of the underlying disease and/or management of the affected animal's environment.

3.5 Special precautions for use

Special precautions for safe use in the target species:
In cases where a bacterial infection is present the product should be used in association with suitable antibacterial therapy. Pharmacologically-active dose levels may result in adrenal insufficiency. This may become apparent particularly after withdrawal of corticosteroid treatment. The treatment should not be suddenly withdrawn. This effect may be minimised by institution of alternate-day therapy if practical. The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency. Corticoids such as prednisolone, exacerbate protein catabolism. Consequently, the product should be carefully administered in old or malnourished animals. Corticoids such as prednisolone should be used with caution in patients with hypertension, epilepsy, burns, previous steroid myopathy, in immunocompromised animals and in young animals as corticosteroids may induce a delayed growth. Treatment with the veterinary medicinal product may interfere with vaccination efficacy. (See section 3.8)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Prednisolone or other corticosteroids may cause hypersensitivity (allergic reactions).
People with known hypersensitivity to prednisolone or other corticosteroids, should avoid contact with the veterinary medicinal product.
Prednisolone may lead to gastrointestinal effects (nausea, vomiting, diarrhoea), headache, and/or hyperactivity if accidentally ingested, particularly in children.
To avoid accidental ingestion, particularly by a child, unused tablets and unused half-tablets should be returned to the container.
In case of accidental ingestion, especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
Corticosteroids can cause foetal malformations. Pregnant women should avoid contact with the veterinary medicinal product.
Immediately wash hands thoroughly after handling the tablets.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Dogs

Very common (>1 animal / 10 animals treated):	Panting, Polyuria, polydipsia, polyphagia[1], Elevated triglyceride[2], hypocortisolaemia[3]
Common (1 to 10 animals / 100 animals treated):	Vomiting, Diarrhoea Opportunistic infection, delayed healing[4]
Uncommon* (1 to 10 animals / 1 000 animals treated):	Behavioural disorder (aggression, restlessness)
Rare* (1 to 10 animals / 10 000 animals treated):	Hyperadrenocorticism (iatrogenic), Cushing's disease (iatrogenic), Diabetes mellitus Hepatomegaly, elevated liver enzymes, elevated serum alkaline

	phosphatase (ALP), eosinopenia, lymphopenia, neutrophilia Muscle wasting Skin thinning, alopecia Gastrointestinal ulceration [5]
Very rare* (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic or hypersensitivity reactions, Pancreatitis
Undetermined frequency (cannot be estimated from available data)	Elevated parathyroid (PTH) concentration, low thyroxine (T4), decreased lactate dehydrogenase (LDH), decreased aspartate aminotransferase (AST), hyperalbuminaemia, hypernatraemia, hypokalaemia[6] Muscle weakness, osteoporosis, inhibition of longitudinal growth of bones Increased weight, water retention, redistribution of body fat Calcinosis cutis

[1] After systemic administration and particularly during the early stages of therapy.

[2]The significant increase in triglycerides noticed can be a part of possible iatrogenic hyperadrenocorticism (Cushing's disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism.

[3]The significant dose related cortisol suppression noticed during therapy is a result of effective doses suppressing the hypothalamic-pituitary-adrenal-axis. Following cessation of treatment, signs of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations.

[4] Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections.

[5] May be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

[6] With long term use.

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 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
Do not use during pregnancy. Laboratory studies have shown evidence of foetal abnormalities during early pregnancy and abortion or early parturition during the later stages of pregnancy.

Glucocorticoids are excreted in the milk and may result in growth impairment in suckling young animals. Use only according to the benefit-risk assessment by the responsible veterinarian in lactating bitches and queens.

Fertility
The safety of the veterinary medicinal product has not been established in males intended for breeding.

3.8 Interaction with other medicinal products and other forms of interaction

Phenytoin, barbiturates, ephedrine and rifampicin may accelerate the metabolic clearance of corticosteroids resulting in decreased blood levels and reduced physiological effect.

The concomitant use of this veterinary medicinal product with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.

Administration of prednisolone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if prednisolone is administered together with potassium depleting diuretics.

Precautions need to be taken when combining use with insulin.

Treatment with the veterinary medicinal product may interfere with vaccination efficacy. When vaccinating with attenuated live vaccines, a two week interval should be observed before or after treatment. Do not use concomitantly with attenuated live vaccines.

3.9 Administration routes and dosage

Oral use
The dose and total duration of treatment, among the authorized posology range, is determined by the veterinarian per individual case depending on the severity of symptoms. The lowest effective dose must be used. To ensure a correct dosage, body weight should be determined as accurately as possible. The break line can be used to divide tablets into equal doses. Check the tablet - look for a score line (a groove indicating where the tablet can be split).
Hold the tablet between your thumbs and forefingers with the scoreline towards you.
Apply gentle, even pressure along the score line until it splits the tablet in two.

Starting dose: 0.5 - 2.0 mg per kg bodyweight once per day.

Administration for one to three weeks at the above dosage levels may be required. For longer term treatment: when after a period of daily dosing the desired effect has been achieved, the dose should be reduced until the lowest effective dose is reached. The reduction of the dose should be made by alternate day therapy and /or by halving the dose with intervals of 5-7 days until the lowest effective dose is reached.

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

An overdose will not cause other effects than those stated in section 3.6.
There is no specific antidote. Signs of overdosage should be treated symptomatically.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB06

4.2 Pharmacodynamics

Prednisolone is a synthetic corticosteroid anti-inflammatory drug belonging to the glucocorticoid family. The main effects of prednisolone are the same as those of glucocorticoids:

Anti-inflammatory action:
The anti-inflammatory properties of prednisolone are expressed at a low dose and are explained by:
- the inhibition of phospholipase A2, which reduces the synthesis of arachidonic acid, a precursor of many proinflammatory metabolites. Arachidonic acid is released from the phospholipid component of the cell membrane by the action of phospholipase A2. The corticosteroids indirectly inhibit this enzyme by inducing the endogenous synthesis of polypeptides, lipocortins, which have an anti-phospholipase action;
- by a membrane stabilising effect, particularly in relation to lysosomes, thus preventing enzymes from being released outside the lysosomal compartment.

Immunosuppressive action:
The immunosuppressive properties of prednisolone are expressed at a higher dose on both the macrophages (slower phagocytosis, decreased flow to inflammatory foci) and the neutrophils and lymphocytes. Administration of prednisolone reduces the production of antibodies and inhibits several complement components.

Antiallergic action:
Like all corticosteroids, prednisolone inhibits the release of histamine by mast cells. Prednisolone is active in all manifestations of allergy as a complement to the specific treatment.

4.3 Pharmacokinetics

Prednisolone is readily absorbed from the gastro-intestinal tract. Peak plasma concentrations are reached 0.5 to 1.5 hours after administration, with a plasma half-life of between 3 and 5 hours. It is distributed to all tissues and body fluids, even in the cerebrospinal fluid. It is extensively bound to plasma proteins, is metabolized in the liver and primarily excreted via the kidneys. It is excreted in the urine as free and conjugated metabolites and parent compound. It has a biological half-life of several hours, making it suitable for alternate-day therapy.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months

5.3 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Store in the original container in order to protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box containing a white 60 ml PE bottle with a white PP twist-off cap and 3g desiccant.

Pack size: Single bottle containing 100 tablets

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

Accord Healthcare B.V.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: To be completed nationally

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

To be completed nationally

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).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PREGLUKORD 25 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:
25 mg prednisolone

3. PACKAGE SIZE

100 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Accord Healthcare B.V.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

POLYETHYLENE BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PREGLUKORD 25 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:
25 mg prednisolone

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

EXP . {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Store in the original container in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Accord Healthcare B.V.

9. BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

PREGLUKORD 25 mg tablets for dogs

2. Composition

Active substance:

Each tablet contains:

25 mg prednisolone

9mm round flat uncoated white tablets with score line and marking ‘A650’ on one side and marking ‘25’ on the other side.

3. Target species

Dogs

4. Indications for use

For the symptomatic treatment or as adjunct treatment of inflammatory and immune-mediated diseases in dogs.

5. Contraindications

Do not use in animals with:
- Viral, mycotic or parasitic infections that are not controlled with an appropriate treatment
- Diabetes mellitus
- Hyperadrenocorticism
- Osteoporosis
- Heart failure
- Renal insufficiency
- Corneal ulceration
- Gastro-intestinal ulceration
- Glaucoma

Do not use in cases of hypersensitivity to the active substance, to other corticosteroids, or to any of the excipients.
See also sections 'Pregnancy and lactation' and 'Interaction with other medicinal products and other forms of interaction'.

6. Special warnings

Special warnings:
Glucocorticoids can produce symptomatic improvements without treating the underlying disease. Where appropriate, use of the product should be combined with treatment of the underlying disease and/or management of the affected animal’s environment.

Special precautions for safe use in the target species:

In cases where a bacterial infection is present the product should be used in association with suitable antibacterial therapy. Pharmacologically-active dose levels may result in adrenal insufficiency. This may become apparent particularly after withdrawal of corticosteroid treatment. The treatment should not be suddenly withdrawn. This effect may be minimised by institution of alternate-day therapy if practical. The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency. Corticoids such as prednisolone, exacerbate protein catabolism. Consequently, the product should be carefully administered in old or malnourished animals. Corticoids such as prednisolone should be used with caution in patients with hypertension, epilepsy, burns, previous steroid myopathy, in immunocompromised animals and in young animals as corticosteroids may induce a delayed growth. Treatment with the veterinary medicinal product may interfere with vaccination efficacy. (See section Interaction with other medicinal products and other forms of interaction).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Prednisolone or other corticosteroids may cause hypersensitivity (allergic reactions).
People with known hypersensitivity to prednisolone or other corticosteroids, should avoid contact with the veterinary medicinal product.
Prednisolone may lead to gastrointestinal effects (nausea, vomiting, diarrhoea), headache, and/or hyperactivity if accidentally ingested, particularly in children.
To avoid accidental ingestion, particularly by a child, unused tablets and unused half-tablets should be returned to the container.
In case of accidental ingestion, especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
Corticosteroids can cause foetal malformations. Pregnant women should avoid contact with the veterinary medicinal product.
Immediately wash hands thoroughly after handling the tablets.

Pregnancy and lactation
Do not use during pregnancy. Laboratory studies have shown evidence of foetal abnormalities during early pregnancy and abortion or early parturition during the later stages of pregnancy.

Glucocorticoids are excreted in the milk and may result in growth impairment in suckling young animals. Use only according to the benefit-risk assessment by the responsible veterinarian in lactating bitches and queens

Fertility
The safety of the veterinary medicinal product has not been established in males intended for breeding.

Interaction with other medicinal products and other forms of interaction:
Phenytoin, barbiturates, ephedrine and rifampicin may accelerate the metabolic clearance of corticosteroids resulting in decreased blood levels and reduced physiological effect.

The concomitant use of this veterinary medicinal product with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.

Administration of prednisolone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if prednisolone is administered together with potassium depleting diuretics.

Precautions need to be taken when combining use with insulin.

Treatment with the veterinary medicinal product may interfere with vaccination efficacy. When vaccinating with attenuated live vaccines, a two week interval should be observed before or after treatment. Do not use concomitantly with attenuated live vaccines.

Overdose:
An overdose will not cause other effects than those stated in Adverse events.

There is no specific antidote. Signs of overdosage should be treated symptomatically

Major incompatibilities:
Not applicable

7. Adverse events

Target species: Dogs

Very common (> 1 animal / 10 animals treated):
Panting, Polyuria, polydipsia, polyphagia[1], Elevated triglyceride[2], hypocortisolaemia[3]
Common (1 to 10 animals / 100 animals treated):
Vomiting, Diarrhoea Opportunistic infection, delayed healing[4]
Uncommon* (1 to 10 animals / 1 000 animals treated):
Behavioural disorder (aggression, restlessness)
Rare* (1 to 10 animals / 10 000 animals treated):
Hyperadrenocorticism (iatrogenic), Cushing's disease (iatrogenic), Diabetes mellitus Hepatomegaly, elevated liver enzymes, elevated serum alkaline phosphatase (ALP), eosinopenia, lymphopenia, neutrophilia Muscle wasting Skin thinning, alopecia Gastrointestinal ulceration [5]
Very rare* (<1 animal / 10 000 animals treated, including isolated reports):
Anaphylactic or hypersensitivity reactions, Pancreatitis
Undetermined frequency (cannot be estimated from available data)
Elevated parathyroid (PTH) concentration, low thyroxine (T4), decreased lactate dehydrogenase (LDH), decreased aspartate aminotransferase (AST), hyperalbuminaemia, hypernatraemia, hypokalaemia[6] Muscle weakness, osteoporosis, inhibition of longitudinal growth of bones Increased weight, water retention, redistribution of body fat Calcinosis cutis

[1] After systemic administration and particularly during the early stages of therapy.

[2] The significant increase in triglycerides noticed can be a part of possible iatrogenic hyperadrenocorticism (Cushing's disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism.

[3] The significant dose related cortisol suppression noticed during therapy is a result of effective doses suppressing the hypothalamic-pituitary-adrenal-axis. Following cessation of treatment, signs of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations.

[4] Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate

existing infections.

[5] May be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

[6] With long term use.

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 its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

The product is intended for:

Dogs: Oral use

Dosage: the following doses are recommended:

DOGS:

The dose and total duration of treatment, among the authorized posology range, is determined by the veterinarian per individual case depending on the severity of symptoms. The lowest effective dose must be used. To ensure a correct dosage, body weight should be determined as accurately as possible. The break line can be used to divide tablets into equal doses.

Recommended Starting dose: 0.5 - 2.0 mg per kg bodyweight per day.

Administration for one to three weeks at the above dosage levels may be required. For longer term treatment: when after a period of daily dosing the desired effect has been achieved, the dose should be reduced until the lowest effective dose is reached. The reduction of the dose should be made by alternate day therapy and /or by halving the dose with intervals of 5-7 days until the lowest effective dose is reached.

9. Advice on correct administration

The break line can be used to divide tablets into equal doses. Check the tablet - look for a score line (a groove indicating where the tablet can be split).
Hold the tablet between your thumbs and forefingers with the scoreline towards you.
Apply gentle, even pressure along the score line until it splits the tablet in two.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original container in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton 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 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: To be completed nationally

Cardboard box containing a white 60 ml PE bottle with a white PP twist-off cap and 3g desiccant.

Pack size:
Single PE bottle containing
100 tablets

15. Date on which the package leaflet was last revised

To be completed nationally

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Accord Healthcare B.V.
Winthontlaan 200, Utrecht, 3526 KV,
Netherlands.
Telephone number: +44 (0) 208 901 3383

Manufacturer responsible for batch release:

Laboratori Fundació DAU
Calle Lletra C De La Zona Franca 12-14, Poligono Industrial De La Zona Franca De Barcelona, Barcelona, 08040, Spain.

17. Other information