Vademécum 2016
Export

SUMARIO

CANIQUANTEL® Plus palatable tablets

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

Praziquantel	50.0 mg
Fenbendazole	500.0 mg

Pharmaceutical form
Tablets for oral use

CLINICAL PARTICULARS

Target species
Dogs and Cats

Indications of use
For the treatment of mixed infections with roundworms and tapeworms inclusive all intestinal stages in dogs and cats

Contraindications
Due to the lack of relevant informations *Caniquantel® plus palatable* tablets should not be used in pregnant animals up to day 39.

Posology and route of administration
The recommended dosage is 5 mg of praziquantel and 50 mg of fenbendazole per kg body weight.
This corresponds to 1 tablet *Caniquantel® plus palatable* per 10 kg body weight.
For the treatment of adult dogs a repeated administration of *Caniquantel® plus palatable* tablets on three consecutive days is recommended.
The tablet is administered directly or mixed with food. Dietary measures or fasting are not necessary.

Withdrawal period(s)
Not applicable

Pharmaceutical particulars

Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 4 years

Special precautions for storage
Dry at temperature < 30° C
Protected from light.

Presentations
1 Blister containing 3 tablets
1 Blister containing 12 tablets
(The presentation varies from country to country)

CANIQUANTEL® Plus XL tablets ad us. vet.

QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains

Praziquantel	100.0 mg
Fenbendazole	1000.0 mg

Pharmaceutical form

Tablets for oral use

CLINICAL PARTICULARS

Target species
Dogs

Indications of use
For the treatment of diagnosed mixed infections with roundworms and intestinal stages of tapeworms in dogs

Ascarids	*Toxocara canis* *Toxascaris leonina*
Hookworms	*Ancylostoma caninum,* *Uncinaria stenocephala*
Whipworms	*Trichuris vulpis*
Tapeworms	*Echinococcus spp.* *Dipylidium caninum* *Taenia spp*. *Mesocestoides spp.*

Contraindications
Due to the lack of relevant informations Caniquantel® Plus XL tablets should not be used in pregnant animals or in pups under three weeks of age.

Posology and route of administration
The recommended dosage is 5 mg of Praziquantel and 50 mg of Fenbendazole per kg body weight.
This corresponds to 1 tablet Caniquantel plus XL per 20 kg body weight or a half tablet for 10 kg bodyweight.
The tablet is administered directly or mixed with food. Dietary measures or fasting are not necessary.
For a treatment of infected dogs a repeated administration on three consecutive days is recommended.

Use during pregnancy and lactation
Not to be used in pregnant animals

Withdrawal period(s)
Not applicable

PHARMACEUTICAL PARTICULARS

Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Special precautions for storage
Store at room temperature (15 – 25°C)
Protected from light.

Presentations
1 Blister containing 3 tablets
(The presentation varies from country to country)

DANILON® Équidos

QUALITATIVE AND QUANTITATIVE COMPOSITION

Suxibuzone (microcapsulated) 150 mg

Pharmaceutical form
Granules

CLINICAL PARTICULARS

Target species
Horses

Indications of use, specifying the target species
Horses: Inflammations. Tendonitis. Contusions. Arthritis. Bursitis, Osteoarthritis, Laminitis, Sprains and soft tissue inflammation.

- Product indicated generally for treatment of pain and inflammation associated with musculo-skeletal conditions in horses.

Contraindications
Special warnings for each target species

Adverse reactions (frequency and seriousness)
Use during pregnancy, lactation or lay

Posology and route of administration

Adult Horses: Loading Dose: 2 sachets/horse, twice daily (2 in the mor-ning and 2 in the evening), for 2 days.
Maintenance Dose: 1 sachet/horse, twice daily (1 in the morning and 1 in the evening), for 3 - 6 days.

Young Horses and Ponies:
Administer half the recommended doses for adult horses.

Withdrawal period(s)
Do not administer to horses which meat is used for human consumption

Pharmaceutical particulars
Shelf life
<Shelf-life of the veterinary medicinal product as packaged for sale> 4 years
<Shelf-life after first opening the immediate packaging >
<Shelf-life after dilution or reconstitution according to directions >

Special precautions for storage
Pack containing 18 sachets of 10 g.
Pack containing 60 sachets of 10 g.

<Not all pack sizes may be marketed.>

The marketing authorization number (s)
EXPORT-1

DERMOCANIS® Alercaps

Nutritional Complement polyunsaturated essential fatty acids

QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:
Every cap contains:

- 500 mg "Borago Officinalis", refined with a high content in polyun-saturated essential fatty acids:
- 175 mg of Linolenic Acid (LA; C 18:2 n-6)
- 100 mg of Gamma- Linolenic Acid (GLA; C18:3 n-6)
- Vitamin E supplement (α-tocopherol): 1 mg

Indications

The balanced imput of essential fatty acids gives to DERMOCANIS ALERCAPS:

- Right skin and hair regeneration in dogs affected by cutaneous dryness, hyperkeratosis, parasitosis, atopies, seborrhoeic dermatitis and other inflammatory processes of the skin.
- Increase of the immunological reply of the organism.
- Setting up of a shining, silky and healthy fur (hear).

Doses and administration

- Oral by forced ingestion or mixed with feed 1 cap per day / 10 kg bodyweight up to a maximum of 4 caps per day during 6 to 8 weeks.

  This routine can be repeated every 6 months concurring to the start of spring and autumn or depending on veterinarian advise.

Presentation

Box containing 30 caps (2 blisters x 15 caps).

DERMOCANIS® Alerdrops

Nutritional Complement polyunsaturated essential fatty acids in oral solution

QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

- Borago Officinalis 100 % pure and refined with a high content in polyun-saturated essential fatty acids:
  - 30 % Linolenic Acid (LA; C 18:2 n-6)
  - 20 % Gamma Linolenic Acid (GLA; C18:3 n-6)
  - Vitamin E supplement (α-tocopherol): 200 ppm.

INDICATIONS

The balanced imput of essential fatty acids gives to DERMOCANIS ALERDROPS:

- Right skin and hear regeneration in dogs affected by cutaneous dryness, hyperkeratosis, parasitosis, atopies, seborrhoeic dermatitis and other inflammatory processes of the skin.
- Increase of the immunological reply of the organism.
- Setting up of a shining, silky and healthy fur (hear).

DOSES AND ADMINISTRATION

- Oral by forced ingestion or mixed with feed 1 – 3 ml per day during 6 - 8 weeks.
  This routine can be repeated every 6 months concurring to the start of spring and autumn or depending on veterinarian advise.

PRESENTATION

Bottle of 60 ml with doser.

DERMOCANIS® Allergies

Antipruritic, Moisturising, Conditioning, Cleansing Shampoo

QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:
Proteins and essential polyunsaturated fatty acids.

Indications

This shampoo has been specifically formulated for the control of the cutaneous symptoms of the canine allergies. Its composition, based on proteins and essential polyunsaturated fatty acids for the epidermis, makes it specially effective in eczematous and inflammatory processes of the dog´s skin. Its excellent tolerance makes it very suitable for its regular use in dogs with delicate, dry or scaling skin.

The essential polyunsaturated fatty acids are fundamental compounds of the cellular membranes, regulating its permeability, flexibility and acting at the same time as precursor of prostaglandin. These fatty acids can not be synthesised by the dog, for this reason has to be supplied orally or topically. In dog with inflammatory dermatitis, the metabolism of the essential fatty acids, that comes from the diet, is changed and the formation of prostaglandin type 1 (PGE1) is reduced, of anti-inflammatory activity, while the formation of prostaglandin type 2 (PGE2), of pro-inflammatory activity, is at normal levels. As a result there is an unbalance between both prostaglandin types, with larger proportion of PGE2, which produces the skin inflammation, oedemas, pruritus, etc.

The Dermocanis ALLERGIAS shampoo gives, directly to the dog's skin, gamma Linoleic acid (GLA; C18:3 n-6), which modulates the PGE1 synthesis which is reduced, regulating the proportions between PGE1 and PGE2. As a result the skin inflammation and the physiological disorders decrease, improving the situation of the corneal stratum. The GLA contribution, therefore, has a determinant beneficial role in the treatment of inflammatory cutaneous disorders, especially in dry and scaling skin, eczema and hyperkeratosis.

The cleansing, moisturising and conditioning power of Dermocanis ALLERGIES, eliminates the dirt and allergens from the skin surface, regulating its flexibility and permeability, giving it back its natural properties and reducing the itching intensity. The improvement of the skin condition increases the animal's well being and when necessary allows the optimal effectively of other more radical treatments.

Administration and dosage

- Wet the animal's hair with lukewarm water.
- Apply the shampoo in different parts and in enough quantity considering the thickness of the hair and size of the animal.
- Extend it by all the body rubbing with the fingers to facilitate the insight of the shampoo.
- Leave the product perform during 3 minutes.
- Rinse with abundant water until the all the foam is gone.

The washing frequency will be determined in function of the intensity of the symptoms and the veterinarians advise. In general is recommended to start with frequent baths, two to three times per week and later cut down the frequency once the process is controlled.

In dogs with dry and delicate skin it is recommended to continue the use of the product as shampoo of regular use.

Precautions

- In case of product contact with the eyes, clean up immediately with lukewarm water.
- The cutaneous allergies in dogs can be produced by autoimmunes processes or by multitude of external allergens (food, pollen, fleas, bacteria, etc.), which simultaneous control is inexcusable for the complete resolution of the process.

Presentation

Bottle of 250 ml

DERMOCANIS® Micosept

Shampoo for the prevention and follow up of mycoses and pyodermas

QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:
2% Undecylenic Acid and 0,3% Triclosan.

Indications

DERMOCANIS® MICOSEPT contains Undecylenic acid, a compound with fungistatic activity against several species of fungal dermatophytes and yeast that might affect dogs. The addition of this ingredient, together with others specific compounds that respect the natural conditions of the skin, as well as its excellent tolerance, makes it very adequate for use of any breed.

Additionally DERMOCANIS MICOSEPT includes Triclosan, biphenolic disinfectant with activity on Gram + and some Gram – bacteria, fungus and yeast.

The regular use of DERMOCANIS® MICOSEPT after treating with antifungal help to consolidate the therapy effects as well as to recover the smooth and shining aspect of the healthy hear.

DERMOCANIS® MICOSEPT is recommended for the hygiene and regular wash of all kinds of dog breeds that had suffered dermatophytosis processes or bacterial infections to follow to the antifungal treatment or specific antibiotic.

Administration and dosage

Wet the animal's hair and apply the shampoo in enough quantity considering the thickness of the hair and size of the animal.
Rub until obtaining foam. Rinse with water and dry avoiding air streams and cold ambient.

The wash with DERMOCANIS® MICOSEPT is recommended for the regular dog hygiene y can be repeated as much as desired depending on the dirtiness level.

Precautions

- In case of product contact with the eyes, clean up immediately with lukewarm water.
- Follow the veterinarian advice.

Presentation

Bottle of 250 ml

DERMOCANIS® Pyodermas

Antimicrobial, Antipruritic, Degreasing, Cleansing Shampoo.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:
Ethyl Lactate 10%.

Indications

This shampoo has been specifically formulated for its use against the superficial and deep pyodermas in dogs.

Its main active ingredient, Ethyl Lactate, is a powerful antimicrobial agent, with broad spectrum, that after its topical application maintains a long residual effect on the skin. At a 10% concentration has a important activity against infections produced by Staphylococcus intermedius, the more common causal agent of the canine pyodermas. Its mechanism of action is based in its high oxidant power. When its in touch with the dog's skin the formation of free radicals are achieved, which lead to the bacterial wall breakdown.

The Ethyl Lactate acts also as antipruritic; keratolytic, producing the elimination of the death cells; degreasing, with activity on the free fatty acids, triglycerides and activity of the sebaceous glands; and facilitate the exit of the exudate from the infected pilous follicles ("flushing action").

The other compounds of Dermocanis PIODERMAS facilitate the interaction of the active ingredient with the dog's skin and gives it, with a low irritating power, a high cleansing and degreasing power that eliminates dirtiness of the skin and gives back its natural properties.

Administration and dosage

- Wet the animal's hair with lukewarm water.
- Apply the shampoo in different parts and in enough quantity considering the thickness of the hair and size of the animal.
- Extend it by all the body rubbing with the fingers to facilitate the insight of the shampoo.
- Leave the product perform during 5 - 10 minutes.
- Rinse with abundant water until the all the foam is gone.

The washing frequency will be determined in function of the intensity of the process and the veterinarians advise. In general is recommended to start with frequent baths, two to three times per week and later cut down the frequency once the process is controlled.
In chronic cases, one weekly application should be enough.
In dogs with dry and delicate skin it is recommended to continue the use of the product as shampoo of regular use.

Precautions

- In deep pyodermas, is convenient to maintain a short hair to facilitate the process control.
- In case of product contact with the eyes, clean up immediately with lukewarm water.
- The dog's pyodermas use to come after other processes, as dermatitis allergies, endocrinophaties, nutritional needs, immunodepresion, alterations of keratinization, ectoparasites, abuse in the use of glucocorticoids, etc., which control is absolutely required for the complete process resolution.
- Follow the vet advise.

Presentation

Bottle of 250 ml

DERMOCANIS® Seborrhoeas

Keratolytic, Keratoplastic, Degreasing, humectant Shampoo.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Salicylic Acid 2%, Salix Alba Extract 3% and Sulphur 2%;

Indications

Dermocanis SEBORREAS has been specifically formulated for the optimal seborrhoeas control, (dry and oily seborrhoea) and the seborrhoeic dermatitis of dogs.

The synergy action of its keratolytics, keratoplastics and degreasing ingredients: salicylic acid, sulphur and Salix Alba extract, softens and eliminates the altered corneous stratum, facilitating the ordered growth of the cells from the basal surface of the epidermis and regulating its posterior keratinization.

SALICILIC ACID: It has multiple effects on the skin. It is a very effective Keratolytic and keratoplastic agent, very effective, moderately antipruriginose and also bacteriostatic. Its keratolytic effect it is produced when it is reduced the density of the intercellular substance and decreasing the skin pHl, which increases the corneous stratum hydration and causing the swelling and falling off its cells. Mixed with coal tar produces an antiseborrhoeic effect for different mechanisms. Also it has a certain direct anti-inflammatory effect.

SULPHUR: Further to its keratolytic and keratoplastic properties, has antifungal, antibacterial, antiparasitive and antipruriginose activity. Its keratoplastic effect if to suit the cystine setting up, that is the important constituent of the corneous extract of the skin. At the same time produces the formation of sulfhídric acid, responsible of its keratolytic effect, and pentatonic acid, holding both of them antifungal and antibacterial effects. There is a synergism between its keratolytics effects and those of the salicylic acid.

SALIX ALBA EXTRACT: is keratoplastic, antipruritic, degreasing and vasoconstrictor. The mechanism by which the Salix Alba shows up its keratoplastic effect is base in the reduction of the speed of division and synthesis of the basal membrane cells´s DNA.
The correct combination of these active ingredients allows a high antiseborrhoeic activity, controlling the odour and the normal scaling, not causing irritation and skin drying. The rest of the compounds of Dermocanis SEBORREAS gives it the antiseptic, cleansing and humidifying properties, taking care of the special characteristics of the skin and the hear of the dogs and giving back its natural shine and smoothness.

Administration and dosage

- Brush the dog before the bath to eliminate the scales and dirtiness excess.
- Wet the animals hear with lukewarm water.
- Shake the bottle and apply the shampoo in different areas and in quantity enough depending on the thickness of the hair and size of the animal.
- Extend it by all the body rubbing with the fingers or a brush to facilitate the insight of the shampoo.
- Leave the product perform during 3 - 5 minutes.
- Rinse with abundant water until the all the foam is gone.
- In severe cases, repeat the process.

The wash frequency will depend on the intensity of the symptoms and vet advice. Generally is recommended to start with frequent baths, 2 – 3 times per week and reducing the frequency as the process is under control.

In case of primary soborrhoeas the use of the shampoo should continue in regular intervals to maintain the dog's skin in perfect conditions.

Precautions

- In dogs with abundant scaly skin is convenient to maintain a short hair to facilitate the process control.
- In persons with allergy to the salicylic acid is recommended the use of gloves while using the product.
- In case of product contact with the eyes, clean up immediately with lukewarm water.
- Do not use in cats.

• The seborrhoeas can be secondary to other sicknesses as ectoparasitoses, pyodermas, dermatophytosis, endocrinophaties, nutritional unbalance or allergies which simultaneous treatment is absolutely required for the complete process resolution.

Presentation

Bottle of 250 ml

DINALGEN® 150 mg/ml solution for injection for cattle

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of the product contains:
Ketoprofen 150 mg

Pharmaceutical form

Solution for injection

CLINICAL PARTICULARS

Target species

Cattle

Indications of use, specifying the target species

Cattle:
- Reduction of inflammation and pain associated with post-partum musculoskeletal disorders and lameness.
- Reduction of fever associated with bovine respiratory disease.
- Reduction of inflammation, fever and pain in acute clinical mastitis.

In combination with antimicrobial therapy where appropriate.

Contraindications

Do not use in animals where there is the possibility of gastro-intestinal ulceration or bleeding, in order not to aggravate their situation.
Do not use in animals suffering from cardiac, hepatic, or renal disease.
Do not use in dehydrated or hypovolemic or hypotensive animals due to the potential risk of increased renal toxicity.
Do not use in animals that have previously shown signs of hypersensitivity to ketoprofen or acetylsalicylic acid or any of the excipients.
Do not use where there is evidence of blood dyscrasia or blood coagulation disturbances

Special warnings for each target species

None.

Adverse reactions (frequency and seriousness)

Intramuscular injection of ketoprofen can cause mild, transient, necrotic subclinical muscular lesions that gradually resolve in the days after completion of treatment. Administration in the neck region minimizes the extension and severity of these lesions.

Due to the mechanism of action of ketoprofen, after repeated administrations, erosive and ulcerative abomasal lesions may occur.

If side effects occur treatment must be stopped and the advice of a veterinarian should be sought.

Use during pregnancy, lactation or lay

The product can be safely used in pregnant or lactating cattle.

Interaction with other medicinal products and other forms of interaction

Concurrent administration of diuretics or potentially nephrotoxic drugs should be avoided since it may increase the risk of renal failure secondary to a diminished renal blood flow caused by inhibition of renal prostaglandin synthesis.
This product must not be administered in conjunction with other NSAIDs or glucocorticosteroids since the risk of gastrointestinal ulceration may be exacerbated.
Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment. The treatment-free period should, however, take into account the pharmacological properties of the products used previously.
Anticoagulants, particularly coumarin derivates such as warfarin should not be used in combination with ketoprofen.
Ketoprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects.

Posology and route of administration
Administer the product via the intravenous or intramuscular route, preferably in the neck region, at a dose of 3 mg of ketoprofen/kg/day, equivalent to 1 ml/50 kg/day of the product. The duration of treatment is 1-3 days, and should be established according to the severity and duration of symptoms.

Withdrawal period(s)
Meat & offal: 2 days
Milk: Zero hours

PHARMACEUTICAL PARTICULARS

Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 28 days

Special precautions for storage
This veterinary medicinal product does not require any special storage conditions.

Presentations
Vial containing 100 ml
Vial containing 250 ml
10 x vial containing 100 ml
10 x vial containing 250 ml

Not all pack sizes may be marketed.

DINALGEN® 300 mg/ml oral solution for cattle and pigs

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of the product contains:
Ketoprofen 300 mg

Pharmaceutical form
Oral solution for use in drinking water.

CLINICAL PARTICULARS

Target species
Fattening Cattle and Pigs

Indications of use, specifying the target species
Fattening Cattle and Pigs:
Treatment for the reduction of pyrexia and dyspnoea associated with respiratory disease in combination with appropriate anti-infective therapy.

Contraindications
Do not administer to suckling calves.
Do not administer to fasting animals or animals with limited access to feed.
Do not use in animals where there is the possibility of gastrointestinal alterations, ulceration or bleeding in order not to aggravate their situation.
Do not use in dehydrated or hypovolemic or hypotensive animal due to the potential risk of increased renal toxicity.
Do not administer to swine fattened at extensive or semi-extensive production farms with access to soil or foreign objects that may damage the gastric mucosa, or with a high parasite burden, or under a severe stress situation. Do not use in animals suffering from cardiac, hepatic, or renal disease. Do not use where there is evidence of blood dyscrasia.

Special warnings for each target species
Water intake of treated animals should be monitored to ensure adequate intake. Individual animal medication, preferably by injection, will be required if daily water intake is insufficient.

Adverse reactions (frequency and seriousness)
The administration of ketoprofen in pigs at the recommended therapeutic dosage may cause superficial and deep erosion of the gastrointestinal tract.

Serious adverse reactions of a gastric nature have very rarely been observed in weaning calves under severe stressful situations (transportation, dehydration, fasting, etc). Cases of gastric ulceration resulting in fatality have been observed in black Iberian pigs, which have been related to being fattened at soil stations with a high parasite burden and the ingestion of foreign bodies. Other cases in intensive farming have been related to forced fasting situations prior or during treatment.

Transitory softening of feces may occur which, in any event, disappears during or at the end of the treatment.

If side effects occur treatment must be stopped for the whole group and the advice of a veterinarian should be sought

Use during pregnancy, lactation
Do not use in pregnant sows.

Interaction with other medicinal products and other forms of interaction
Interactions between Ketoprofen and the most commonly used antibiotics have not been specifically investigated. Pre-treatment with other anti-inflammatory or corticosteroid substances may result in additional or increased adverse effects. Accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment.

The treatment-free period should, however, take into account the pharmacological properties of the products used previously. This product must not be administered in conjunction with other NSAIDs or glucocorticosteroids since gastrointestinal ulceration may be exacerbated.
Ketoprofen is highly bound to plasma proteins. The concomitant administration of substances that are also highly plasma protein bound may compete with ketoprofen with the possibility of consequent toxic effects due to the unbound fraction of the drug. Anticoagulants, particularly coumarin derivates such as warfarin should not be used in combination with ketoprofen. Concurrent use with diuretics or potentially nephrotoxic drugs has a higher risk to develop renal disturbances secondary to the diminishing blood flow caused by the inhibition of prostaglandins.

Posology and route of administration

Dosage: Cattle
3 mg of ketoprofen/kg bw/d orally (equivalent to 1 ml/100 kg bw/d of the finished product)

Pigs

1.5 - 3 mg of ketoprofen/kg bw/d orally (equivalent to 0.5 - 1 ml/100 kg bw/d of the finished product). Dose of 1.5 mg/kg is effective in the treatment of mild to moderate processes (body temperature <41°C). Dose must be increased up to 3mg of ketoprofen /kg bw to treat more severe cases.

Treatment should be given for one day. It can be continued for another 1-2 days after a risk/benefit assessment by the responsible veterinarian.

METHOD OF ADMINISTRATION

The veterinary medicinal product is administered by the oral route, diluted in drinking water. Administration over a 24 hour period is recommended. Medicated water should be the only water supply during the period of treatment and should be refreshed every 24 hours. The product may be put directly into the header tank or introduced via a water proportioner pump. Once the treatment period has finished, the animals should be given unmedicated water.

The animals must have ad libitum access to food and medicated water before and during treatment. Start the treatment of recumbent animals with the parenteral form. To prevent overdosing, pigs should be grouped according to bodyweight and an average bodyweight estimated as accurately as possible.

The water intake of the animals to be treated should be measured before calculating the total amount of product to be administered each day. In order to calculate accurately the rate of incorporation of the product in drinking water, it is necessary to estimate the mean weight and the consumption of water of the animals to be treated, based on the average for the days immediately before treatment.

In order to ensure the consumption of the proper dosage throughout the whole of the treatment, it will be necessary to adjust the incorporation rate into the drinking water on a daily basis.

Withdrawal period(s)

Meat and offal: 24 hours

PHARMACEUTICAL PARTICULARS

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:	3 years
Shelf-life after first opening the immediate packaging:	3 months
Shelf-life after dilution or reconstitution according to directions:	24 hours

Special precautions for storage

Keep the bottle tightly closed

Presentations

Bottle of 500 ml

Not all pack sizes may be marketed

DINALGEN® 60 mg/ml solution for injection for pigs

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of the product contains:
Ketoprofen 60 mg

Pharmaceutical form
Solution for injection

CLINICAL PARTICULARS

Target species
Pigs

Indications of use, specifying the target species
Pigs:

Reduction of pyrexia in cases of respiratory disease and Postpartum Dysglactia Syndrome Mastitis, Metritis, Agalactiae (MMA syndrome) in sows, in combination with appropriate anti-infective therapy.

Contraindications
Do not use in animals where there is the possibility of gastro-intestinal ulceration or bleeding, in order not to aggravate their situation.
Do not use in animals suffering from cardiac, hepatic, or renal disease.
Do not use in dehydrated or hypovolemic or hypotensive animals due to the potential risk of increased renal toxicity.
Do not use in animals that have previously shown signs of hypersensitivity to ketoprofen or aspirin or any of the excipients.
Do not use where there is evidence of blood dyscrasia or blood coagulation disturbances

Special warnings for each target species
Since gastric ulceration is a common finding in PMWS (Post-weaning Multisystemic Wasting Syndrome), the use of ketoprofen in pigs affected by this pathology is not recommended, in order not to aggravate their situation.

Adverse reactions (frequency and seriousness)
Intramuscular injection may be followed by transient irritation at the injection site.
The administration of ketoprofen in pigs at the recommended therapeutic dosage may cause superficial erosion and/or superficial ulceration of the gastrointestinal tract.
If side effects occur treatment must be stopped and the advice of a veterinarian should be sought.

Use during pregnancy, lactation or lay
The safety of ketoprofen has been investigated in pregnant laboratory animals (rats, mice, rabbits) and cattle.
No adverse effects were noted. As the safety of ketoprofen has not been assessed in pregnant sows, the product should be used in this case only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
Interactions between Ketoprofen and the most commonly used antibiotics have not been investigated.
Concurrent administration of diuretics or potentially nephrotoxic drugs should be avoided since there is an increase of renal disturbances. This is secondary to the diminished blood flow caused by the inhibition of prostaglandins.
This product must not be administered in conjunction with other NSAIDs or glucocorticosteroids since gastrointestinal ulceration may be exacerbated.
Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment. The treatment-free period should, however, take into account the pharmacological properties of the products used previously.
Anticoagulants, particularly coumarin derivates such as warfarin should not be used in combination with ketoprofen.

Ketoprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects.

Posology and route of administration

Administer via the intramuscular route at a dose of 3mg/Kg bodyweight of ketoprofen, equivalent to lml/20Kg bodyweight of product, on a single occasion. Depending on the response observed and treatment may be repeated at intervals of 24 hours for a maximum of three treatments. Each injection should be given at a different site.

Withdrawal period(s)

Meat & offal: 3 days

PHARMACEUTICAL PARTICULARS

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging : 28 days

Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

Presentations

Vial containing 100 ml
Vial containing 250 ml
10 x vial containing 100 ml
10 x vial containing 250 ml

Not all pack sizes may be marketed.

DOBETIN® Solution for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

THIAMINE chloral-hydrate (Vit. B1)	10.000 mg
CYANOCOBALAMIN (Vit. B12)	100 mg

Pharmaceutical form
Solution for injection

CLINICAL PARTICULARS

Target species
Cattle, pigs, dogs, cats, horses

Indications of use
Treatment for vitamins B1 and B12 deficiencies, asthenia, paresis, myoclonia, myoglobinuria, organic debility, neuritis, nervous disorders, muscle fatigue, liver diseases.

Contraindications
None

Special warnings for each target species
None.

Use during pregnancy, lactation or lay
The product can be safely used in pregnant or lactating cattle.

Posology and route of administration
By intra-muscular o intravenous route.

Catlle:	Calves:	3 - 6 ml / animal
	Adult animals:	10 ml / animal
Pigs:	Piglets:	1 - 1,5 ml / animal
	Adult animals:	1,5 - 4 ml / animal
Dogs and cats:		0,5 ml / animal
Horses:		
	Young horses:	3 - 6 ml/animal
	Adult animals:	10 ml/animal

Withdrawal period(s)
None

PHARMACEUTICAL PARTICULARS

Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 28 days

Special precautions for storage
Keep out of the reach of the light, in a fresh and dry place.

Presentations
Vial containing 100 ml

LEISGUARD 5 mg/ml oral suspension for dogs

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance
Domperidone 5 mg

Excipients:
Methyl parahydroxybenzoate (E218) 1.80 mg
Propyl parahydroxybenzoate (E216) 0.20 mg
Quinoline yellow (E104) 0.20 mg

Pharmaceutical form
Oral suspension
Yellow suspension

CLINICAL PARTICULARS

Target species
Dogs

Indications for use, specifying the target species
To reduce the risk of developing an active infection and clinical disease in case of contact with *Leishmania infantum*, through the enhancement of the cell-mediated immune response.

The efficacy of the product has been demonstrated in dogs under multiple natural parasite exposure in zones with high infection pressure.

Control of clinical progression of canine leishmaniosis at early stages of the disease (dogs with low to moderate positive antibody levels and mild clinical signs such as peripheral lymphadenopathy or papular dermatitis).

Contraindications
Do not use whenever stimulation of gastric motility might be dangerous eg. In the presence of gastrointestinal haemorrhage, mechanical obstruction or perforation.
Do not use in animals with a known hypersensitivity to domperidone or any of the excipients.
Do not use in animals with prolactin-secreting pituitary tumor.
Domperidone is metabolized by the liver, therefore it should not be administered to animals with liver failure.

Special warnings for each target specie
In case of severe infections, adequate aetiological treatment should be established in order to lower the parasitic load prior to consider a treatment with this veterinary medicinal product. In all cases, and taking into account the highly variable evolution of the disease, close patient follow up is recommended in order to adapt the treatment to the clinical stage of the animal, as required.

Adverse reactions (frequency and seriousness)
At the dosages and duration recommended, this veterinary medicinal product is very well tolerated.

In clinical trials rare cases of galactorrhoea during treatment with Leisguard were reported. This is considered a consequence of the prolactine peaks induced by domperidone, which disappear after treatment discontinuation.

Use during pregnancy or lactation
Pregnancy - Reproduction studies were performed in laboratory animals with no evidence of drug related teratogenic or embryotoxic effects. Signs of maternal toxicity were not seen in laboratory animals at doses 20 times higher than the recommended dose. However, there are no adequate and well controlled studies in pregnant bitches; therefore this drug should be used during pregnancy only in accordance with the benefit/risk assessment by the responsible veterinarian.

Lactation - Administration of domperidone to lactating females of several species has been shown to induce an increase of milk production. Administration of Leisguard to lactating bitches is likely to induce the same effect.

Interaction with other medicinal products and other forms of interaction

Cabergoline is a dopamine agonist that inhibits prolactin release from the pituitary gland. Therefore, its effects are antagonistic to those of domperidone.
Do not administer with stomach antacids such as omeprazole, cimetidine, or antacids.
Domperidone should not be used with dopaminergic drugs such as dopamine or dobutamine.

Amounts to be administered and administration route

0.5 mg/kg/d, equivalent to 1 ml/10 kg of Leisguard, once daily, during 4 consecutive weeks.

Leisguard may be administered directly into the mouth or mixed with food. To ensure a correct dosage, body weight should be determined as accurately as possible
Shake well before use
There are several schedules of dosing:

A) for reducing the risk of developing an active infection and clinical disease in case of contact with *Leishmania infantum*,

In seronegative animals that have never showed any sign of *Leishmania spp.* infection, but live or travel to an endemic area, domperidone treatments should be programmed, taking into account the temporary prevalence of leishmaniosis vectors (*Phlebotomus spp.*) in the geographic area of the patient location or destination.

In high prevalence areas or in climates with a long infective season, one treatment every four months should be administered. In the Mediterranean area, it would be advised to treat in June, October and February.
In low prevalence areas, one treatment period at the beginning of the infective season and another treatment shortly after the end may suffice.

In all cases, the treatment strategy must be established by the attending veterinarian in accordance with the local incidence of the disease and temporary presence of the infective vectors.

B) For the Control of clinical progression of canine leishmaniosis at early stages of the disease

The treatment should be started immediately after diagnosis in order to help animals to self-limit the disease.

Treatment with Leisguard may be repeated as needed, in accordance with the clinical and serological follow up performed by the attending veterinarian.

Withdrawal period(s)

Not applicable.

PHARMACEUTICAL PARTICULARS

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months
Shelf-life after first opening the immediate packaging: 8 months

Special precautions for storage

Store in the original package.
Protect from light.

Nature and composition of immediate packaging

A 60 ml high-density polyethylene (HDPE) bottle closed with a low density polyethylene (LDPE) adapter and a HDPE child-proof screw-cap.
Carton box with one bottle and two syringes (LDPE barrel, polystyrene (PS) plunger and LDPE piston), one graduated up to 1,5 ml and the other graduated up to 5 ml.

OTOCLEAN® dogs and cats

Otic solution - 18 plastic monodose vials of 5 ml

Composition

Lactic acid
Salicylic acid
Plant extracts
Transcutol
Excipient

Properties

OTOCLEAN® contains keratolytic, cerumenolitic, emollient, hygienizing and moisturising ingredients that confers the product excellent properties for the hygiene and care of the external ear canal of dogs and cats, keeping it free of dirtiness, cerumen and secretions.

Species

Dogs and Cats.

Way of use

Apply OTOCLEAN® in each ear canal of the dog/cat in quantity enough considering the animal size:

- Large animals, apply one vial (5 ml) in each ear.
- Small and medium size animals apply the content of ½ vial in each ear.

Let OTOCLEAN ® act and do not apply any other substance before 15 - 30 minutes.

Indications and frequency of use

The frequency of the use of OTOCLEAN® will depend on the claim considered in every case.

- OTITIS PREVENTION.

In breeds prone to suffer otitis, as a consequence of the anatomy of its ears (Cocker, Setter, Caniche, etc,...), it is convenient to apply OTOCLEAN® as a routine hygiene practice. One application every 5-7 days, will maintain the external ear canal in optimal conditions.

- EARS HYGIENE, Disagreeable odour, etc.

In animals showing accumulation of cerumen and dirt often a disagreeable odour is perceived. In these cases is convenient to apply OTOCLEAN® in each ear canal every 24 hours, during 8 consecutive days and from then delaying further applications (every 2-3 days) upon de the obtained response until ending with completely clean ear ducts.

- SYNERGYSTIC WITH OTITIS TREATMENTS.

In animals suffering otitis, to improve the efficacy of therapeutic treatments it is convenient to clean the ear duct removing the dirt, cerumen and secretions. Applying Otoclean 30 minutes prior to the application of the therapeutic solution improves the response and results of the treatment.

For the adequate ear hygiene it is recommended a complementary clean up of the external auditive canal with TOPP OIDOS wipes.

Presentation

Pack containing 18 monodose plastic vials of 5 ml.