Animalcare Limited
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Danilon Equidos Gold 1.5 g Granules for horses and ponies

Species:	Horses only
Active ingredient:	Suxibuzone
Product:	Danilon Equidos Gold 1.5 g Granules for horses and ponies
Product index:	Danilon Equidos Gold 1.5 g Granules for horses and ponies
Withdrawal notes:	Not to be used in animals intended for human consumption. Treated horses may never be slaughtered for human consumption.
Incorporating:	

Qualitative and quantitative composition

Each 3 g sachet contains:

Active substance:

Suxibuzone (microencapsulated) 1.5 g

Excipient(s):

Tartrazine (E102)

Mannitol

Sucrose

Povidone K-30

Sodium saccharin

Ethyl Cellulose 20

Pharmaceutical form

Yellow granules

Clinical particulars

Target species

Horses and ponies.

Indications for use, specifying the target species

Treatment of pain and inflammation associated with musculo-skeletal conditions in the horse eg osteoarthritic conditions, bursitis, laminitis and soft tissue inflammation.

Contraindications

Do not use in animals with renal, hepatic or cardiac disorders.

Do not use in animals where there is the possibility of gastro-intestinal ulceration or bleeding.

Do not use in animals where there is evidence of a blood dyscrasia.

Do not use in known cases of hypersensitivity to the active substance or any of the excipient

Special warnings

NSAIDs can cause inhibition of phagocytosis and hence, in the treatment of inflammatory conditions associated with bacterial infections appropriate antimicrobial therapy should be instigated.

Special precautions for use

Do not exceed the stated dose or duration of treatment. Dosage should be kept to a minimum for alleviation of symptoms.

During treatment of very young animals (less than 12 weeks) where development of their hepatic or renal function may be incomplete, or in aged animals which may have these functions impaired, as well as in ponies, additional risk may be involved. In these cases, the posology should be adjusted and patients monitored closely.

During treatment, do not restrict the consumption of water. Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there may be an increased risk of

renal failure.

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

Tartrazine may cause allergic reactions

In case of known hypersensitivity to suxibuzone or any of the excipients, avoid contact with the product.

Wash hands after use.

Use in a well-ventilated area. To avoid exposure to the granules, part-sachets should not be used. Avoid inhaling any dust when opening sachet and mixing with feed. Avoid contact with skin, eyes and mucosa. In case of accidental contact, wash with plenty of clean water. In case of accidental ingestion, seek medical advice immediately and show this label to the physician.

Adverse reactions (frequency and seriousness)

After continued use, or at high doses gastro-intestinal changes may occur (very rare frequency). With a very rare frequency blood dyscrasias and renal alterations may be found, especially in animals with restricted access to water.

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay, therefore use during this period is not recommended.

Interaction with other medicinal products and other forms of interaction

Suxibuzone and its metabolites may be highly bound to plasma proteins and compete with other highly bound drugs eg sulphonamides, warfarin; or it may itself be displaced to produce an increase of non-bound pharmacologically active concentrations which could lead to toxic effects. Drug compatibility must be closely monitored when adjunctive therapy is required.

Do not administer together with other NSAIDs concurrently or within 24 hours of each other.

Concurrent administration of potentially nephrotoxic drugs should be avoided.

Amounts to be administered and administration route

For oral administration. When added to a portion of feed the product will be accepted by most horses.

The following should be used as a guide, according to individual response:

Horses

For a 480 kg bodyweight horse, the contents of 2 sachets should be administered twice daily (equivalent to 12.5 mg of suxibuzone/kg/day) for 2 days, followed by 1 sachet twice daily (6.25 mg of suxibuzone/kg/day) for 3 days.

Thereafter, 1 sachet daily (3.1 mg of suxibuzone/kg/day) or on alternate days, or the minimum dose frequency necessary for a satisfactory clinical response.

Ponies

Ponies should receive only half the dose rate recommended for horses.

For a 240 kg bodyweight pony, the contents of 1 sachet should be administered daily (equivalent to 6.25 mg of suxibuzone/kg/day) for 2 days, followed by 1 sachet on alternate days.

Thereafter, reduce to the minimum dose frequency necessary for a satisfactory clinical response.

Hay, as part of the diet, may delay the absorption of suxibuzone and so the onset of clinical effect. It is advisable not to feed hay immediately prior to, or with the veterinary medicinal product.

If no clinical response is evident after 4-5 days, discontinue treatment and reconsider the diagnosis.

Part sachets should not be used.

Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of accidental continuous overdose, the following symptoms may be observed:

• Thirst, depression, anorexia and weight loss

• Gastrointestinal disorders (irritation, ulcers, diarrhoea and blood in the faeces)

• Altered blood profiles and haemorrhages

• Hypoproteinemia with ventral oedema causing hemoconcentration, hypovolemic shock and circulatory collapse.

• Renal failure and fluid retention.

If signs of intolerance appear, discontinue treatment and establish symptomatic therapy.

A slow intravenous perfusion of a solution of sodium bicarbonate, which leads to urine alkalinisation, increases the clearance of the product.

Withdrawal period

Not to be used in animals intended for human consumption. Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

Pharmacological particulars

Pharmacodynamic properties

Suxibuzone is a Non-Steroidal Anti-inflammatory Drug (NSAID) synthetically derived from pyrazolone with anti-inflammatory, antipyretic and analgesic properties with low ulcerogenic potential.

When mixed with concentrate feed, the product was shown to be palatable to horses. Its mechanism of action is based on the inhibition of the cyclooxygenase (enzyme which catalyzes the synthesis of prostaglandins, prostacyclines and thromboxanes from arachidonic acid). The therapeutic effects are mainly due to the inhibition of the biosynthesis of prostaglandines, which act as peripheral mediators of pain and trigger the synthesis of endogen pyrogens and mediators in the inflammatory process. It also inhibits platelet aggregation.

The therapeutic effect of suxibuzone relies entirely on the activity of its active metabolites. Strong anti-inflammatory activity has been shown for phenylbutazone and oxyphenbutazone. The third metabolite gamma-hydroxyphenbutazone is considered to be pharmacologically inactive.

Pharmacokinetic particulars

After oral administration suxibuzone is readily absorbed and most of it is metabolised by the hepatic microsomal system producing phenylbutazone, oxyphenbutazone and gamma-hydroxyphenylbutazone. No unaltered parent compound can be detected in plasma after oral administration of suxibuzone to horses. These active metabolites have a high degree of affinity for plasma proteins and are eliminated mainly through urine, as glucoronide conjugates, but also, in a small percentage, through faeces. Less than 1% is eliminated through saliva and milk.

After the administration of a single 6.25 mg/kg oral dose of the parent compound phenylbutazone reaches its maximum plasma concentration (9.9±2.3 µg/ml) at 11±3 hours after administration with an elimination half life of 7.1±0.5 h. Oxyphenbutazone reaches its maximum (1.5±0.4 µg/ml) at 15±5 hours after administration.

As happens with other NSAID´s the duration of the clinical response is much longer than the plasma half-life. Significant concentrations of both active metabolites are found in synovial fluid for at least 24 hours after administration.

Pharmaceutical particulars

List of excipients

Tartrazine (E102)

Mannitol

Sucrose

Povidone K-30

Sodium saccharin

Ethyl Cellulose 20

Major incompatibilities

Not applicable.

Shelf life

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

Special precautions for storage

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

Nature and composition of immediate packaging

3 g laminated opaline/aluminium polyethylene sachets

Cartons containing 18 or 60 sachets

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Marketing Authorisation Holder (if different from distributor)

Ecuphar Veterinaria S.L.U.

C/Cerdanya, 10-12 Planta 6º

08173 Sant Cugat del Vallès

Barcelona

Spain

Marketing Authorisation Number

UK: Vm 46037/4006

Significant changes

Date of the first authorisation or date of renewal

DATE OF FIRST AUTHORISATION: 10 September 2020

Date of revision of the text

REVISED: February 2022

Any other information

Nil

Legal category

Legal category: POM-V

GTIN

GTIN description: Danilon Equidos Gold 60 sachets

GTIN: 5420036941040