

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Danilon equidos 1.5 g Oral Granules for horses and ponies (PL)
Danilon equidos 1.5 g Granules for horses and ponies (AT/DE)
Danilon equidos 1.5 g/10 g Granules for horses and ponies (NO)
Danilon equidos 1.5 g Granules (BE, CZ, EE, IS, HU, LV, LT, RO, SK, SI)
Danilon Equidos (DK)
Suxilon 1.5g Granules for top dressing (only for UK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 g sachet contains

Active substance:

Suxibuzone (microencapsulated) 1.5 g

Excipient(s):

Quinoline yellow (E 104) 2.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules
Yellow and odourless granules.

4. CLINICAL PARTICULARS

4.1 Target species

Horses and ponies.

4.2 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.

4.3 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 cases of known hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings for each target species

-

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

4.5 Special precautions for use

4.5.i Special precautions for use in animals

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, doses should be accurately calculated 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.

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

Wear suitable gloves. Wash hands after use.

Use in a well-ventilated area. Avoid inhaling any dust when opening sachet and mixing with feed. In case of accidental contact with eyes, wash immediately with plenty of clean water. In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.

4.6 Adverse reactions (frequency and seriousness)

After continued use, or at high doses gastro-intestinal changes may occur. Occasionally blood dyscrasias and renal alterations may be found, especially in animals with restricted access to water.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation, therefore use during these periods is not recommended.

4.8 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.

4.9 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 necessary for a satisfactory clinical response.

Ponies (breeds of less than 149 cm high at the withers when full grown)

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 1/2 sachet daily (3.1 mg of suxibuzone/kg/day) for 3 days or 1 sachet on alternate days.

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

For administration of less than one sachet, use the measuring scoop provided. One full level scoop contains 5 g granules (equivalent to 1/2 sachet) and up to the green line level contains 2.5 g granules (equivalent to 1/4 sachet).

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 this medicinal product.

See also 4.4.

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

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

In cases of continuous overdose, the following signs 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.

4.11 Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids, butylpyrazolidines, suxibuzone.

ATC vet code: QM01AA90

5.1 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, prostacyclins and thromboxanes from arachidonic acid). The therapeutic effects are mainly due to the inhibition of the biosynthesis of prostaglandins, which act as peripheral mediators of pain and trigger the synthesis of endogenous 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 γ -hydroxyphenylbutazone is considered to be pharmacologically inactive.

5.2 Pharmacokinetic particulars

After oral administration suxibuzone is readily absorbed and most of it is metabolised by the hepatic microsomal system producing phenylbutazone, oxyphenbutazone and γ -hydroxyphenylbutazone. No unaltered parent compound can be detected in plasma after oral administration of suxibuzone to horses or ponies. These active metabolites have a high degree of affinity for plasma proteins and are eliminated mainly through urine, as glucuronide 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 (10 μ g/ml) at 4-5- hours after administration. Oxyphenbutazone reaches its maximum (2.1 μ g/ml) at 15 hours after administration. Both metabolites have an elimination half life of 5-6 h.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quinoline yellow (E 104)
Mannitol
Sucrose
Povidone K-30
Sodium saccharin
Ethyl Cellulose 20

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years
Shelf life after first opening of the sachet: 7 days.

6.4. Special precautions for storage

After opening a sachet re-seal as well as possible between doses.
This medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Carton containing 18 x 10 g or 60 x 10 g coated paper, aluminium foil and polyethylene sachets with 5 g spoon (when level) and 2.5 g increment dosing device.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Ecuphar Veterinaria S.L.U.
C/Cerdanya, 10-12 Planta 6º
08173 Sant Cugat del Vallés
Barcelona, Spain

8. MARKETING AUTHORISATION NUMBER

...

9. DATE OF FIRST AUTHORISATION

14 June 2011

10 DATE OF REVISION OF THE TEXT

...