# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Danilon Equidos 1.5 g Granules for top dressing

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 g sachet contains:

**Active substance:**

Suxibuzone (microencapsulated) 1.5 g

**Excipient:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Quinoline yellow (E 104) | 2.5mg |
| Mannitol | |
| Sucrose | |
| Povidone K-30 | |
| Sodium saccharin | |
| Ethyl Cellulose 20 | |

Yellow and odourless granules.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Horses and ponies.

### 3.2 Indications for use for each target species

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

### 3.3 Contraindications

Do not administer to animals with renal, hepatic or cardiac disorders; where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.
Do not use in cases of known hypersensitivity to the active substance or any of the excipients.

Avoid use in dehydrated, hypovolemic or hypotensive animals as there is an increased risk of renal failure.

### 3.4 Special warnings

Do not administer to horses prior to taking part in a competition.

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

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Use in very young or aged animals and ponies may involve additional risk. Adjust the dose to bodyweight and closely monitor clinical response.

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

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 this label to the physician.

Special precautions for the protection of the environment:

Not applicable.

## 3.6 Adverse events

Horses and ponies:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Allergic reactions |
| Undetermined frequency (cannot be estimated from the available data) | Gastrointestinal irritation or ulceration[1]<br><br>Renal insufficiency[1]<br><br>Blood dyscrasia[1]<br><br>Hepatic disorder[1] |

[1] Due to the mechanism of action of NSAIDs (inhibition of prostaglandin synthesis)

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

The safety of the veterinary medicinal product has not been established during pregnancy lactation.

## 3.8 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 e.g. 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.

## 3.9 Administration routes and dosage

For oral use.
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

**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 veterinary medicinal product.

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

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

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.

### 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 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.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QM01AA90

### 4.2 Pharmacodynamics

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 γ-hydroxyphenbutazone is considered to be pharmacologically inactive.

### 4.3 Pharmacokinetics

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. 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 (10 µg/ml) at 4-5- hours after administration with an elimination half-life of 5-6 h. Oxyphenbutazone reaches its maximum (2.1 µg/ml) at 15 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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Not applicable.

### 5.2 Shelf life

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

### 5.3 Special precautions for storage

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

### 5.4 Nature and composition of immediate packaging

Carton containing 18 x 10 g or 60 x 10 g laminated opaline/aluminium polyethylene sachets with 5 g scoop (when level) and 2.5 g increment dosing device.

Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar Veterinaria S.L.U.

## 7. MARKETING AUTHORISATION NUMBER

Vm 46037/4000

## 8. DATE OF FIRST AUTHORISATION

02 August 2001

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

July 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

*Gavin Hall*
Approved: 20 August 2025