1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Danilon Equidos NF 1.5 g/sachet granules in sachet for horses and ponies

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g sachet contains

Active substance

Suxibuzone 1.5 g (equivalent to 1.59 g suxibuzone microencapsulated)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Tartrazine (E-102)	0.37 mg
Mannitol	
Sucrose	
Povidone K-30	
Sodium saccharin	
Ethyl Cellulose 20	

Yellow granules.

3. CLINICAL INFORMATION

3.1 Target species

Horse (non-food producing) and Pony (non-food producing).

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals with gastrointestinal disorders, particularly when there is a possibility of gastrointestinal ulceration or bleeding in order not to aggravate the condition.

Do not use when there is an evidence of blood dyscrasia or coagulation disorders.
Do not use in animals with cardiac, hepatic or renal disorders.
Do not use in animals of less than one month old.
Do not use with other nonsteroidal anti-inflammatories (NSAIDs). See section 3.8.

3.4 Special warnings

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 administer this product.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product has a narrow safety margin. Do not exceed the stated dose or duration of treatment.

The use of this veterinary medicinal product is not recommended in animals of less than one month old. During treatment of animals of less than 12 weeks, or in aged animals as well as in ponies, additional risk may be involved. In these cases, adjust the posology and closely monitor clinical response.

Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there may be an increased risk of renal failure. During treatment, do not restrict the consumption of water and administer a feeding regime low in proteins, nitrogen and chloride.

Do not use in the treatment of visceral pain.

In case of long-term treatment, it is recommended to regularly perform blood analyses.

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

Tartrazine and possibly suxibuzone may cause allergic reactions.
People with known hypersensitivity to suxibuzone or tartrazine should avoid contact with the veterinary medicinal product.
Avoid inhaling any dust when opening the sachet and mixing with feed. Use in a well-ventilated area.
In case of accidental contact with eyes, skin or mucous membranes, wash immediately with plenty of clean water.
This veterinary medicinal product may cause gastrointestinal effects after accidental ingestion, particularly by children. Store the sachets in a safe place away from children, especially when the sachet is opened.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.
Do not smoke, eat or drink while manipulating the veterinary medicinal product.

Other precautions:

The use of this veterinary medicinal product in competition must be done in accordance with the recommendations and advice of the competent authority as suxibuzone is considered a prohibited substance (doping) by national and international authorities.

3.6 Adverse events

Horse (non-food producing) and Pony (non-food producing).:

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

	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 its local representative 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 this veterinary medicinal product has not been established during pregnancy and lactation. Do not use during this period of time.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration with other NSAIDs increases the risk of adverse reactions. Do not administer together with other NSAIDs within 24 hours of each other. Do not administer concurrently with other NSAIDs, glucocorticoids, diuretics or anticoagulants.

Suxibuzone and its metabolites are highly bound to plasma proteins and may compete with other highly bound drugs, which could lead to toxic effects.

Concurrent administration of potentially nephrotoxic drugs should be avoided as there is an increased risk of renal toxicity.

3.9 Administration routes and dosage

Oral use.

The veterinary medicinal product is palatable, i.e., it is usually taken voluntarily by the majority of horses when added to a portion of feed.

Adult horses

Initial dose:
6.25 mg of suxibuzone/kg bodyweight, twice daily (equivalent to 1 sachet of 3g for each 240 kg bodyweight horse twice daily) for 2 days.

Maintenance dose:
3.1 mg of suxibuzone/kg bodyweight, twice daily (equivalent to 1 sachet of 3g for each 480 kg bodyweight horse twice daily) 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 and foals
Half the dose recommended for horses.

For administration of less than one sachet, use the measuring scoop provided. One full level scoop contains 0,75 g granules (equivalent to 1/4 sachet). Two times the same level scoop contains 1,5 g granules (equivalent to 1/2 sachet).

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)

Toxic effects can appear due to an accidental overdose or due to the additive effect or synergic when administered with other drugs (especially other NSAIDs). Ponies are more susceptible to these effects.

In case of overdose, the following symptoms may be observed:
- Thirst, depression, anorexia and weight loss
- Gastrointestinal disorders (irritation, ulcers, colic, diarrhoea and blood in the faeces)
- Blood dyscrasia and haemorrhages
- Hypoproteinemia with ventral oedema causing hemoconcentration, hypovolemic shock and circulatory collapse.
- Renal insufficiency that could derive in renal failure.

In these cases, discontinue treatment and establish symptomatic therapy, a diet rich in proteins and a slow intravenous perfusion of a solution of sodium bicarbonate, which leads to urine alkalinisation and 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 applicable

Do not use 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.

Its mechanism of action is based on the inhibition of the cyclooxygenase (enzyme which catalyses the synthesis of prostaglandins, prostacyclines and thromboxanes from arachidonic acid). It has been demonstrated that the therapeutic effects are 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 has a slight uricosuric action and inhibits platelet aggregation.

The therapeutic effect of suxibuzone relies entirely on the activity of its active metabolites (phenylbutazone and oxyphenbutazone). The third metabolite γ -hydroxyphenbutazone is considered to be pharmacologically inactive.

4.3 Pharmacokinetics

After oral administration suxibuzone is rapidly absorbed. Compared to the duration of the clinical response the elimination half-life is relatively short. Suxibuzone has a high affinity to plasma proteins and passes in this form into inflammatory tissue, thus displaying a limited tissue diffusion. Most of the

suxibuzone is metabolised by the hepatic microsomal system producing phenylbutazone, oxyphenbutazone and γ -hydroxyphenylbutazone and their glucoronic conjugates. It is excreted mainly through urine but also, in a small percentage, through saliva and milk.

After the administration of a single 6.25 mg/kg oral dose of suxibuzone, the main metabolite phenylbutazone reaches its maximum plasma concentration (10 µg/ml) at 11 +/-3.5 hours after administration. Oxyphenbutazone reaches its maximum plasma concentration (1,5 µg/ml) at 15 +/- 5.3 hours after administration. Both metabolites have an elimination half-life of 7-8 h. The excretion of phenylbutazone is faster when urine is alkaline than when it is acidic.

As with other NSAIDs 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: 5 years.
Shelf life after first opening the immediate packaging: 7 days

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Carton containing 18 x 3 g or 60 x 3 g laminated opaline/aluminium polyethylene sachets.
Measuring device: high density polyethylene spoon of 1.25 ml capacity (equivalent to 0.75 g of product)

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 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

Ecuphar NV

7. MARKETING AUTHORISATION NUMBER(S)

VPA10491/014/001

8. DATE OF FIRST AUTHORISATION

10/05/2024

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

12/12/2024

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).