B. PACKAGE LEAFLET

PACKAGE LEAFLET

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 1.5 g Granules for top dressing (only for UK)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Laboratorios Dr. ESTEVE, S.A.
Sant Martí, s/n. Polígon Industrial
08107 Martotelles (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Danilon equidos 1.5 g Granules
Suxilon 1.5 g Granules for top dressing (only for UK)
Suxibuzone

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Per 10 g sachet
Active substance: Suxibuzone (microencapsulated) 1.5 g
Excipient(s): Quinoline yellow (E 104) 2.5 mg
Yellow odourless granules

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses and ponies.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

For administration of less than one sachet, use the measuring scoop provided. One full level scoop contains 5 g granules (equivalent to ½ 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.
If no clinical response is evident after 4-5 days, discontinue treatment and reconsider the diagnosis.
See point 12. Special warning(s)

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
After opening a sachet re-seal as well as possible between doses.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening of the sachet: 7 days.

When the sachet is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the sachet should be discarded should be worked out. This discard date should be written in the space provided.

keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

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.

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 dehydrated, hypovolemic or hypotensive animals as there is an increased risk of renal failure.
User warnings: 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.

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

Interaction with other medicinal product 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.

Overdose (symptoms, emergency procedures, antidotes):In cases of accidental 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.

Incompatibilities: None known

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product in accordance with guidance from your local waste regulation authority.

UK only: Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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15. OTHER INFORMATION

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 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. After oral administration suxibuzone is readily absorbed and most of it is metabolised by the hepatic microsomal system producing phenylbutazone, oxyphenbutazone and γ-hydroxyphenylbutazone. 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.

PRESENTATIONS
Sachets containing 10 g of granules.
Each carton contains 18 or 60 sachets and a spoon of two capacities.
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
For animal treatment only.
To be supplied only on veterinary prescription.
Keep sachet in outer carton.
This medicinal product is a prescription only medicine to be used in accordance with the directions of a veterinary surgeon.

MARKETING AUTHORISATION NUMBER:

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