PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Danilon Equidos Gold 1.5 g Granules for horses and ponies

Suxibuzone

2. STATEMENT OF ACTIVE SUBSTANCES

Suxibuzone 1.5 g

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

18 x 3 g
60 x 3 g

5. TARGET SPECIES

Horses and ponies.

6. INDICATIONS

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

7. METHOD AND ROUTE OF ADMINISTRATION

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

HORSES:
For a 480 kg bodyweight horse, the contents of 2 sachets should be administered twice daily for 2 days, followed by 1 sachet twice daily for 3 days.
Thereafter, 1 sachet daily 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 once daily for 2 days, followed by 1 sachet on alternate days.
Thereafter, reduce to the minimum dose frequency necessary for a satisfactory clinical response.

Read the package leaflet before use.

Part sachets should not be used.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNINGS, IF NECESSARY

Do not use in animals with renal, hepatic or cardiac disorders.
Do not use in animals where there is a possibility of gastro-intestinal bleeding or ulceration. Do not use in animals where there is evidence of blood dyscrasia.
Do not use in known cases of hypersensitivity to the active substance or any of the excipients.
Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is an increased risk of renal failure.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. POM - V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 46037/4006

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Danilon Equidos Gold 1.5 g Granules for horses and ponies
Suxibuzone

2. QUANTITY OF THE ACTIVE SUBSTANCE

Suxibuzone 1.5 g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3 g

4. ROUTE OF ADMINISTRATION

DOSAGE AND ADMINISTRATION
For oral administration. When added to a portion of feed, the product will be accepted by most horses.
HORSES: For 480 kg bodyweight horse, 2 sachets twice daily for 2 days, followed by 1 sachet twice daily for 3 days. Thereafter, administer 1 sachet daily or on alternate days, or the minimum dose frequency necessary for a satisfactory clinical response.

Refer to package leaflet for information on correct treatment of ponies.

5. WITHDRAWAL PERIOD

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.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
For further information, including user warnings, see package leaflet.
POM-V. To be supplied only on veterinary prescription.

Keep out of the sight and reach of children.
Vm 46037/4006

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

PACKAGE LEAFLET

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 Vallès
Barcelona
Spain

Manufacturer responsible for batch release
Recipharm Parets, S.L.U.
C/ Ramón y Cajal, 2,
Parets del Vallés,
08150 Barcelona (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Danilon equidos gold 1.5 g Granules for horses and ponies
Suxibuzone

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

Per 3 g sachet:
Active substance: Suxibuzone (microencapsulated) 1.5 g
Excipients: Tartrazine (E-102) 0.37 mg

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 a possibility of gastro-intestinal bleeding or ulceration.
Do not use in animals where there is evidence of blood dyscrasia.
Do not use in known cases of 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 (very rare frequency). With a very rare frequency 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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}

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 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.
Part sachets should not be used.

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

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

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, the posology should be adjusted 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.

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.

Pregnancy and Lactation:
Studies have not been carried out in the horse to establish safe use 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 case 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, hypovolaemic 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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2023

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.

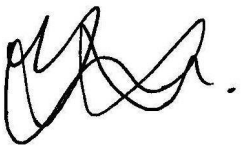
PRESENTATIONS
Sachets containing 3 g of granules.

Each carton contains 18 or 60 sachets.
Not all pack sizes may be marketed.

Local Representative
Animalcare Ltd,
Moorside, Monks Cross,
York, YO32 9LB,
United Kingdom

For animal treatment only.
To be supplied only on veterinary prescription.
This medicinal product is a prescription only medicine to be used in accordance with the directions of a veterinary surgeon.

MARKETING AUTHORISATION NUMBER:
Vm 46037/4006



Approved: 12 January 2023