Data Sheet

Presentation:
Free flowing white/cream powder for oral administration, containing 1 g micro-encapsulated Phenylbutazone per sachet.
Preservative: Sodium Paracombin 0.15 % w/w

Indications:
Equipalazone 1 g Oral Powder is indicated in the treatment of musculoskeletal disorders in horses and ponies where the anti-inflammatory and analgesic properties of phenylbutazone can offer relief; for example, in lameness associated with osteoarthritic conditions, acute and chronic laminitis, bursitis and carpitis, and in the reduction of post-surgical soft tissue reaction.

Dosage and administration:
Dependent on individual response, but as a guide:
Horses 450 kg (1000 lb) bodyweight: Two sachets to be administered twice on day one (equivalent to 8.8 mg/kg/day), followed by one sachet twice daily for four days (4.4 mg/kg/day), then one sachet daily, or on alternate days, sufficient to keep the horse comfortable (2.2 mg/kg/day).
Ponies 225 kg (500 lb) bodyweight: One sachet (4.4 mg/kg/day) on alternate days.
Adjust dose according to bodyweight.
Discontinue treatment if no response is evident after four to five days' treatment.
For ease of administration, Equipalazone 1 g Oral Powder may be mixed with a small quantity of bran or oats.

Contraindications, warnings etc:
Treated horses may never be slaughtered for human consumption.
The therapeutic index of phenylbutazone is low.
Do not exceed the stated dose or the duration of treatment.
Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia or hypersensitivity to the product.
Do not administer other NSAIDs concurrently, or within 24 hours of each other.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.
Use in any animal less than six weeks of age, or in aged animals, may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal as there is a risk of increased renal failure.
Concurrent administration of potentially nephrotoxic drugs should be avoided.
It is preferable that NSAIDs, which inhibit prostaglandin synthesis, are not administered to animals undergoing general anaesthesia until fully recovered.
Use during pregnancy should be avoided whenever possible, particularly during the first trimester.
Response to long-term therapy should be monitored at regular intervals by a veterinary practitioner.

Operator warnings:
The product should be handled with care at all times to reduce the risk of accidental ingestion, skin contact or dust inhalation.
If accidental skin or eye contact occurs, the site should be washed immediately with water.
If the product is ingested, seek medical advice immediately and show the product packaging.
Advice to doctors: gastric lavage (emesis in children) should be performed urgently.
Charcoal haemoperfusion has also been shown to be beneficial. Treatment should then be administered symptomatically.

Pharmaceutical precautions:
Store in a dry place.
Do not store above 25°C.
Dispose of any unused product and empty containers in accordance with guidance from your national waste regulation authority.

General precautions:
Keep out of the reach and sight of children.
For animal treatment only.
NSAIDs can cause inhibition of phagocytosis and hence, in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

Legal category:
POM-V UK: Prescription Only Medicine – Veterinarian
POM IE: Prescription Only Medicine
Veterinary medicinal product authorised for use in UK and Ireland.
UK only: To be supplied only on veterinary prescription

Package quantities:
Boxes of 32 and 100 sachets.

Further information:
The clinical effect of phenylbutazone can be evident for at least three days following cessation of administration. This should be borne in mind when examining horses for soundness.
Some authorities (including the Jockey Club) regard phenylbutazone as a "prohibited substance" under the rules of competition. Therefore, use of this product in a competition horse should be in accordance with the recommendations/advice of the relevant competition authorities.

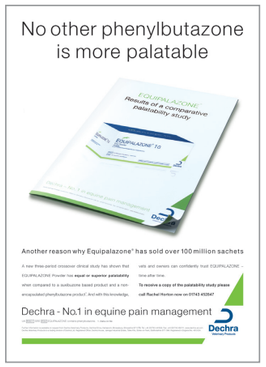
Marketing authorisation holder:
Dechra Limited, Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, UK.

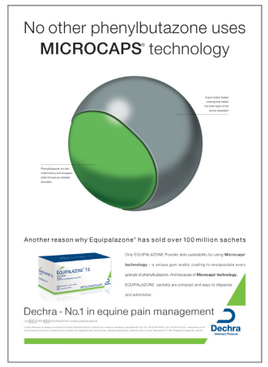
Distributor:
Dechra Veterinary Products, Cartmel Drive, Harlescott, Shrewsbury, Shropshire, SY1 3TB, UK.

Marketing authorisation numbers:
UK: Vm 10434/4005
IE: VPA 10799/5/1

Date of preparation:
July 2007

Further information available on request.





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Equipalazone®

Results of a comparative palatability study

Dechra – No. 1 in equine pain management

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Study Methods

In a 3-period, 3-treatment crossover study, the palatability of Equipalazone Powder with its unique microencapsulation (MICROCAPS® technology) was compared with a UK suxibuzone product and a UK non-encapsulated phenylbutazone product.

Eighteen horses were randomly allocated to one of three treatment groups, ranking horses by decreasing, day one, body weights.

The products were administered as an oral top dress to the morning grain ration. Palatability was monitored by measuring the total grain consumed and through the use of subjective scoring methods.

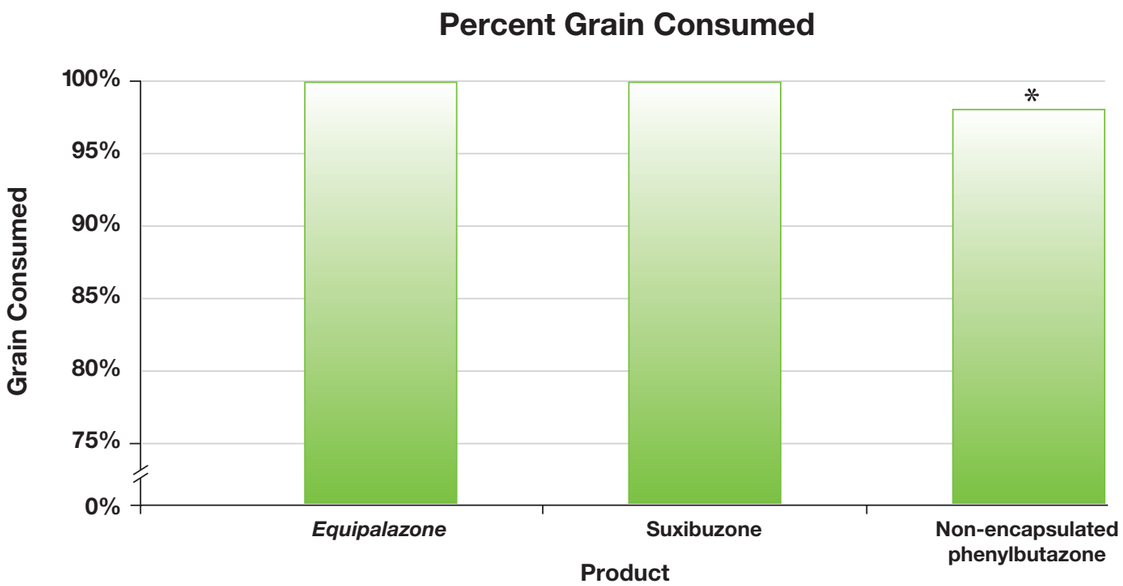
percentage of grain consumed was then calculated, using the formula:

$$\text{Amount fed} - \text{amount remaining} = \text{Amount consumed}$$

$$\frac{\text{Amount consumed}}{\text{Amount fed}} \times 100 = \text{\% Grain consumed}$$

Results: Percent Grain Consumed

Based on the average over the three days of the study, the percentage of grain consumed was lower when top-dressed with the non-microencapsulated phenylbutazone product as compared to either *Equipalazone* or the suxibuzone product. This difference was statistically significant. There was no statistically significant difference in consumption between *Equipalazone* and the suxibuzone product.



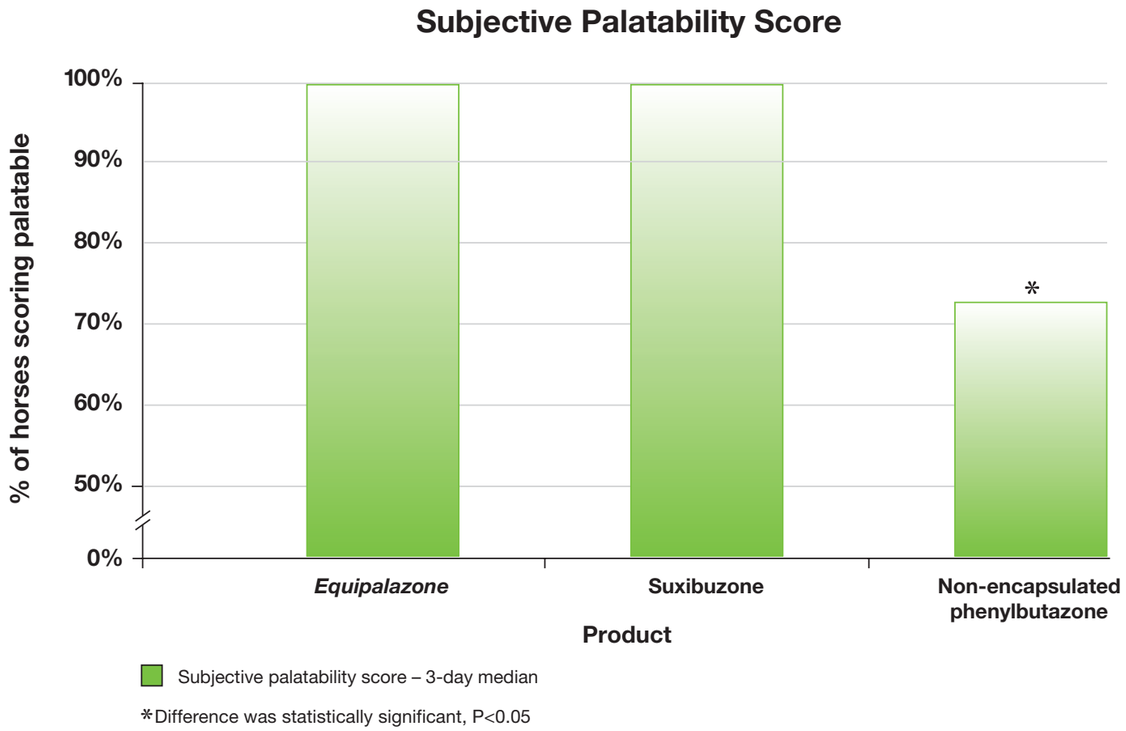
Percent Grain Consumed

Each horse was allowed 20 minutes to consume its allotted morning portion of grain. The amount of grain remaining in the feeder was weighed to determine the total amount of grain consumed. The

Subjective Palatability Assessment

An observer, who was blinded to the treatment group to which the horse was assigned, scored palatability according to the scale on the right:

PALATABILITY	
SCORE	OBSERVATION
0	Not palatable
1	Moderately palatable
2	Palatable



Results: Subjective Palatability Assessment

Based on the 3-day median, the palatability was observed to be lower when the morning grain ration was top-dressed with the non-encapsulated phenylbutazone product as compared to either *Equipalazone* or the suxibuzone product. This difference was statistically significant. There was no statistically significant difference between the observed consumption of *Equipalazone* and the suxibuzone product.

Conclusion

These results show that *Equipalazone* Powder and the suxibuzone product are **equally palatable,** while the non-encapsulated phenylbutazone product is **less palatable.**

Data on file

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