1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro-Dynam Oral Powder, 1 g phenylbutazone per sachet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each 5g sachet contains phenylbutazone 1g

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White Oral Powder

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

The product is indicated for the treatment of musculo-skeletal conditions where relief from pain and a reduction in the associated inflammation is required e.g. in lameness associated with osteoarthritic conditions, bursitis, laminitis and soft tissue inflammation, particularly where continued mobility is considered desirable.

It is also of value in limiting post surgical inflammation, myositis and other soft tissue inflammation.

Pro-Dynam can be used as an anti-pyretic where this is considered advisable e.g. in viral respiratory infections.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding or where there is evidence of a blood dyscrasia.

Do not administer other NSAIDs concurrently or within 24 hours of each other.

4.4 Special warnings

The clinical effects of phenylbutazone can be evident for at least three days following cessation of therapy. This should be borne in mind when examining horses for soundness.

Some equestrian authorities regard phenylbutazone as a ‘prohibited substance’ within their rules.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the stated dose as the therapeutic index of phenylbutazone is low.

Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, animals may require careful clinical management.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal as there is a potential risk of increased renal toxicity.

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

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

Wash hands after use.

Avoid contact with the eyes. In case of accidental eye contact, irrigate eyes with plenty of clean water. If irritation persists seek medical advice.

Care should be taken to avoid inhaling or ingesting the powder.

In the event of accidental inhalation or ingestion seek medical advice and show the product packaging.

4.6 Adverse reactions (frequency and seriousness)

In common with other NSAIDs that inhibit prostaglandin synthesis, there may be gastric and/or renal intolerance. This is usually associated with overdosage and such events are rare. Recovery is usual on cessation of treatment and following the initiation of supportive symptomatic therapy (see 4.10 for further information).

4.7 Use during pregnancy and lactation

Pregnancy:
Care should be exercised if administered to pregnant mares. Although no adverse effects of phenylbutazone on the foetus or maintenance of pregnancy have been reported during field use, no definitive safety studies have been carried out in the mare.
Foetotoxic effects of phenylbutazone have been recorded in experimental animal species at high dose levels.

Lactation:
Phenybutazone does not readily cross the blood milk barrier.

If the administration of phenylbutazone to pregnant or lactating mares is considered essential the potential benefits should be weighed against the potential hazard to the mare and/or foal.

Avoid use around time of parturition.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of potential nephrotoxic drugs should be avoided.

Phenylbutazone is extensively bound to plasma proteins. It may displace other drugs that are highly protein bound e.g. some sulphonamides, warfarin or it may itself be displaced to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.

Concurrent therapy with other therapeutic agents should be undertaken with caution due to the risk of metabolic interactions. Phenylbutazone may interfere with the metabolism of other drugs e.g. warfarin, barbiturates, with resultant toxicity.

There is evidence to indicate that the pharmacokinetics of penicillin products may be affected by concurrent administration of products containing phenylbutazone with a possible reduction of therapeutic efficacy, since tissue penetration may be reduced. The distribution of other drugs given concurrently may also be affected.

4.9 Amounts to be administered and administration route

Should be administered by mouth.

For each 450 kg (1000 lbs) bodyweight the following dosage guide should be used according to individual response:

Day 1: Two sachets twice daily (equivalent to 4.4 mg/kg on each occasion).

Day 2-4: One sachet twice daily (equivalent to 2.2 mg/kg on each occasion) followed by one sachet daily (2.2 mg/kg daily) or on alternate days as required.

If no response is evident after 4-5 days, discontinue treatment. Hay may delay the absorption of phenylbutazone and so the onset of a clinical effect. It is advisable not to administer hay immediately prior to, or during the administration of Pro-Dynam.

For ease of administration Pro-Dynam may be mixed with a quantity of bran or oats.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdosing may result in gastric and large intestinal ulceration and general enteropathy. Renal papillary damage may also occur with impaired renal function. Subcutaneous oedema, especially under the jaw may become evident due to plasma protein loss.

There is no specific antidote. If signs of possible overdosage occur, treat the animal symptomatically.

4.11 Withdrawal period(s)

Not for use in horses 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids,
ATCvet code: QM01AA01

5.1 Pharmacodynamic properties

Phenylbutazone is a pyrazolone non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and anti-pyretic activity. These pharmacodynamic effects are achieved by the inhibition of prostaglandin synthetase (cyclo-oxygenase).

5.2 Pharmacokinetic particulars

The plasma elimination half life of phenylbutazone in the horse varies from 3.5 – 8.0 hours. Normally peak plasma levels are achieved approximately 2-3 hours after administration. Oral bioavailability is high but absorption may be delayed if administered on a full stomach. Hay in the diet may further delay absorption due to binding and so the onset of a clinical effect.

Phenylbutazone binds heavily to plasma albumin.

Phenylbutazone is metabolised in the liver to oxphenbutazone, which also has similar pharmacological activity. Further metabolism takes place to gamma-hydroxyphenylbutazone Excretion is mainly *via* the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose Monohydrate
Methylhydroxypropylcellulose

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Paper sachets with an outer lamination of aluminium foil and an inside lamination of polyethylene, containing 5g of white powder. Supplied in cartons of 100 sachets.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

8. MARKETING AUTHORISATION NUMBERS

UK: Vm 24883/4000
Ireland: VPA 10803/1/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

UK: 13-04-1994 / 13-04-2007
Ireland: 01-10-1990 / 01-10-2005

10. DATE OF REVISION OF THE TEXT

April 2009

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.