PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro-Dynam Oral Powder 1 g phenylbutazone per sachet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 5 g sachet contains 1 g phenylbutazone

3. PHARMACEUTICAL FORM

Oral Powder

4. PACKAGE SIZE

100 sachets

5. TARGET SPECIES

Horses declared as not intended for human consumption.

6. INDICATION(S)

Pro-Dynam is a non-steroidal anti-inflammatory drug (NSAID) for use in horses. It is indicated for the treatment of musculoskeletal 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 there is considered advisable e.g. in viral respiratory infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pro-Dynam 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)

Day2-4 One sachets 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 feed hay immediately prior to, or during the administration of Pro-Dynam.

For ease of administration Pro-Dynam may be added to a quantity of bran or oats.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mekuvej 9

DK-7171 Uldum

Denmark

16. MARKETING AUTHORISATION NUMBER(S)

Legal category and marketing authorisation numbers:

UK: Vm 24883/4000 POM-V

IE: VPA 10803/1/1/ POM

17. MANUFACTURER’S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Foil sachets}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro-Dynam Oral Powder 1 g phenylbutazone per sachet

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

This 5g sachet contains:

1 g phenylbutazone.

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

5 g

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

Not to be used 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 passport legislation.

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET FOR:

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

Dechra Veterinary Products A/S

Mekuvej 9

DK-7171 Uldum

Denmark

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pro Dynam Oral Powder 1 g Phenylbutazone per Sachet

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

A fine white odourless powder for oral administration to horses presented in sachets, each containing 1 g Phenylbutazone.

4. INDICATION(S)

Pro-Dynam is a non-steroidal anti-inflammatory drug (NSAID) for use in horses. It is indicated for the treatment of musculoskeletal 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 there is considered advisable e.g. in viral respiratory infections.

5. 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 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 or glucocorticoids concurrently or within 24 hours of each other.

6. ADVERSE REACTIONS

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 **Overdose** section for further information).

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

7. TARGET SPECIES

Horses declared as not intended for human consumption.

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

Pro-Dynam 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)

Day2-4 One sachets 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 feed hay immediately prior to, or during the administration of Pro-Dynam.

For ease of administration Pro-Dynam may be added to a quantity of bran or oats.

9. ADVICE ON CORRECT ADMINISTRATION

The therapeutic index of Phenylbutazone is low. Do not exceed the stated dose or the duration of treatment.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

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

Do not use after the expiry date which is stated on the carton.

12. SPECIAL WARNING(S)

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.

For Animal Treatment Only

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.
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.

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.

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. Avoid use around time of parturition.
Lactation: Phenylbutazone 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.

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.
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.

Overdose (symptoms, emergency procedures, antidotes)
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.

Incompatibilities
None known.

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

Any unused 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

UK: 15-12-2010
IE: 20-12-2010

15. OTHER INFORMATION

To be supplied only on veterinary prescription.

For animal treatment only.

Veterinary medicinal product authorised for use in UK and IE.

Legal category and marketing authorisation numbers:

UK: Vm 24883/4000 POM-V

IE: VPA 10803/1/1/ POM

Package quantities
Boxes of 100 x 5 g sachets, each sachet containing 1 g phenylbutazone.

For further information please contact the local representative:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
UK
031684-02 [