SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodyl 20mg Tablets for Dogs (UK)
Carprieve 20mg Tablets for Dogs (France)
Carprogesic 20mg Tablets for Dogs (Germany, Belgium, Luxembourg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Ingredient:
Carprofen 20 mg

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
A white/off white circular tablet of diameter 8 mm, 20 embossed on one side and a single breakline on the other side.

4. CLINICAL PARTICULARS

4.1 Target Species:

Dogs

4.2 Indications for Use, Specifying the Target Species:

In the dog: Reduction of inflammation and pain caused by musculo-skeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post-operative pain.

4.3 Contraindications:

Do not use in cats.

Do not use in puppies less than 4 months of age.
Do not use in case of hypersensitivity to active substance or to any of the excipients.
Do not use in dogs suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia.
Refer to section 4.7

4.4 Special Warnings for Each Target Species:

Refer to Sections 4.3 and 4.5.

4.5 Special Precautions for Use:

i. Special precautions for use in animals

Use in aged dogs may involve additional risk. If such use cannot be avoided, such dogs may require careful clinical management.
Avoid use in any dehydrated, hypovolaemic or hypotensive dog, 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 infection, appropriate concurrent antimicrobial therapy should be instigated.
Refer to section 4.8
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

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

In the event of accidental ingestion of the tablets, seek medical advice and show the doctor the package leaflet. Wash hands after handling the product.

4.6 Undesirable Effects (Frequency and Seriousness):

Typical undesirable effects associated with NSAIDs such as vomiting, soft faeces/diarrhea, faecal occult blood, loss of appetite and lethargy have been reported. These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, use of the product should be stopped and the advice of a veterinarian should be sought.

As with other NSAIDs there is a risk of rare renal or idiosyncratic hepatic adverse events.

4.7 Use During Pregnancy, Lactation or Lay:

Studies in laboratory species (rat and rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose. The safety of the veterinary medicinal product has not been

established during pregnancy and lactation. Do not use in pregnant or lactating bitches.

4.8 Interaction with other Medicinal Products and Other Forms of Interaction:

Do not administer NSAIDs and glucocorticoids concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Concurrent administration of potential nephrotoxic drugs should be avoided.

4.9 Amounts to be Administered and Administration:

For oral administration.
4mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen/kg bodyweight/day given as a single daily dose or in 2 equally divided doses. The dose may be reduced subject to clinical response.
Duration of treatment will be dependent upon the response seen. Long term treatment should be under regular veterinary supervision.
Do not exceed stated dose.
To extend analgesic and anti-inflammatory cover post-operatively parenteral pre-operative treatment with an injectable carprofen product may be followed with Carprofen Tablets at 4mg/kg/day for 5 days.

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

Doses up to three times the recommended dosage are reported to be without adverse effect in dogs. There is no specific antidote to carprofen but general supportive therapy as applied to clinical overdosage with NSAID's should be applied.

4.11 Withdrawal Period(s):

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug
ATC Vet Code: QM01AE91

5.1 Pharmacodynamic properties:

Carprofen, (±)-6-chloro-α-methylcarbazole-2-acetic acid, is a non-steroidal anti-inflammatory drug (NSAID). It is a derivative of phenylpropionic acid and a member of the arylpropionic acid class of

NSAIDs. As a representative of the 2-arylpropionic family, it contains a chiral center at C_2 of the propionic moiety and therefore, exists in 2 sterioisomeric forms, the (+)-S and (-)-R enantiomers.

Carprofen possesses anti-inflammatory, analgesic and anti-pyretic activity. Carprofen like most other NSAIDs is an inhibitor of the enzyme cyclo-oxygenase of the arachidonic acid cascade. However the inhibition of prostaglandin synthesis by carprofen is slight in relation to its anti-inflammatory and analgesic potency. The precise mode of action of carprofen is not clear.

5.2 Pharmacokinetic properties:

Absorption is rapid with >90% absorption after oral administration. The volume of distribution is small and carprofen is highly bound to plasma proteins. Biotransformation of carprofen occurs in the liver to form the ester glucuronide and two 1-O-acyl-β-D-glucuronide diastereoisomers. These are secreted in the biliary tract and excreted in the faeces. The Cmax is 28.51 µg/ml and the AUC is 237.33 µg/ml.hour.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipient(s):

Microcrystalline cellulose
Lactose monohydrate
Croscarmellose sodium
Povidone K30
Sodium laurilsulfate
Magnesium stearate

6.2 Incompatibilities:

None.

6.3 Shelf-Life:

Shelf-life of the veterinary medicinal product as packaged for sale
Tubs: 3 years
Blister strips: 2 years

6.4 Special Precautions for Storage:

Do not store above 25ºC.
Store in a dry place.

6.5 Nature and Composition of Immediate Packaging:

Polypropylene tubs with white polyethylene snap secure caps.

PVC/Aluminium/Orientated polyamide blisters with aluminium lidding foil.

Pack sizes: Blisters
Box of 10 blisters, each blister contains 10 tablets.

Pack sizes: Tubs
Tub containing 100 tablets.

Not all pack sizes may be marketed.

6.6 Special Precautions for the Disposal of Unused Veterinary Medicinal Products or Waste Materials Derived From the Use of Such Products:

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

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4265

9. DATE OF FIRST AUTHORISATION

Date: 05 October 2006.

10. DATE OF REVISION OF THE TEXT

Date: October 2012