SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product

Norodyl 100 mg Tablets for Dogs (UK & DK)
Carprieve 100 mg Tablets for Dogs (Germany and France)
Norocarp 100 mg Tablets for Dogs (all other CMS)

2. Qualitative and Quantitative Composition

Each tablet contains:

Active Substance
Carprofen 100 mg

Excipients
Tartrazine (E102) 1.2 mg

For the full list of excipients, see section 6.1

3. Pharmaceutical Form

Tablet
A yellow circular tablet of 8 mm diameter, embossed “100” on one side and a single breakline on the other side.
The tablets can be divided into equal halves.

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 musculoskeletal 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 pregnant or lactating bitches.
Do not use in puppies less than 4 months of age.

Do not use in animals with known hypersensitivity to the 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.

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 a use cannot be avoided, such dogs may require a reduced dosage and careful clinical management.
Avoid use in any dehydrated, hypoproteinemic, 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.

(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 ***Adverse Reactions (Frequency and Seriousness):***

Typical undesirable effects associated with NSAIDs such as vomiting, soft faeces/diarrhoea, 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 other 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 per kg bodyweight per day given as a single dose or in two equally divided doses. The daily 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 the stated dose.
To extend analgesic and anti-inflammatory cover post-operatively parenteral pre-operative treatment with an injectable Carprofen product may be followed with Norodyl Tablets at 4mg/kg/day for up to 5 days.

Return any halved tablets to the original pack and use at the next administration. Any halved tablets remaining after the last administration of the product must be discarded.

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

There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs 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 possess 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-ÿ-D-glucuronide diastereoisomers. These are secreted in the biliary tract and excreted in the faeces. The C_{max} is 28.51 µg/ml and the AUC is 237.33 µg/ml.hour.

6. Pharmaceutical Particulars

6.1 ***List of Excipient(s):***

Tartrazine (E102)
Microcrystalline Cellulose
Lactose Monohydrate
Croscarmellose Sodium
Povidone K30
Sodium laurilsulphate
Magnesium Stearate

6.2 ***Incompatibilities:***

Not applicable.

6.3 ***Shelf-Life:***

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4 ***Special Precautions for Storage:***

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

6.5 ***Nature and Composition of Immediate Packaging:***

Norodyl Tablets are supplied in either:

Polypropylene Snap Secure Tubs containing 14, 30 or 100 tablets, sealed with a low density white Polyethylene Snap Secure Cap, or Aluminium-Aluminium blister strips with strips of 10 tablets in cartons containing 10, 20, 30, 50, 60, 70, 100, 140, 180, 200, 250, 280, 300, 500 or 1000 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, if appropriate:***

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

7. Name or Corporate Name and Address or Registered Place of Business of the Marketing Authorisation Holder

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

8. MARKETING AUTHORISATION NUMBER

Vm: 02000/4282

9. DATE OF FIRST AUTHORISATION

Date: 21 July 2009

10. DATE OF REVISION OF THE TEXT

Date: July 2014

Approved: **25/07/2014**