

**PACKAGE LEAFLET
NOROCARP TABLETS FOR DOGS**

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

[To be completed nationally]

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodyl 100mg Tablets for Dogs (UK & DK)
Paracarp 100mg Tablets for Dogs (Germany)
Norocarp 100mg Tablets for Dogs (RMS and all other CMS)
Carprofen.

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

A yellow circular tablet of 8 mm diameter, embossed “100” on one side and a single breakline on the other side.

Active Substance
Carprofen 100 mg

Excipients
Tartrazine (E102) 1.2 mg

The tablets can be divided into equal halves.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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.

7. TARGET SPECIES

Dogs.

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

To extend analgesic and anti-inflammatory cover post-operatively parenteral pre-operative treatment with an injectable Carprofen product may be followed with Norocarp Tablets at 4mg/kg/day for up to 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

Do not exceed the stated dose.

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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

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

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the Blister and Carton after "EXP"

12. SPECIAL WARNINGS

Use in aged animals, may involve additional risk. If such 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.

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.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating bitches.

Do not exceed the stated dose. There is no specific antidote for carprofen overdose but general supportive therapy, as applied to clinical overdose with NSAIDs should be applied.

User Warnings:

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.

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

Any unused veterinary medicinal 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

2018-12-28

15. OTHER INFORMATION

LEGAL CATEGORY:

[To be completed nationally]

PACKAGE QUANTITIES:

Norocarp Tablets are supplied in either:

Polypropylene Snap Secure Tubs containing 14, 30 or 100 tablets, sealed with a white

Polyethylene Snap Secure Cap.

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.