

SUMMARY OF PRODUCT CHARACTERISTICS
Veterinarian Prescription only medicine
For animal use only

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICIN

Norocarp 20 mg tablets veterinary
Norocarp 50 mg tablets veterinary
Norocarp 100 mg tablets veterinary

2. ACTIVE INGREDIENTS

Each 20 mg tablet contains: Carprofen 20mg
Each 50 mg tablet contains: Carprofen 50mg
Each 100mg tablet contains: Carprofen 100ng
Norocarp 100mg tablets contains Tartrazine (E102) 1.2 mg

For a full list of excipients, see section 12 "further information"

3. Indications for use

In Dogs: 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.

Therapeutic Group: Non steroidal anti inflammatory drug (NASID)

4. Contraindications

Do not use in cats.

Do not exceed the stated dose.

Do not use in pregnant or lactating bitches.

Do not use in puppies less than 4 months of age.

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.

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

5. 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.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting

adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.it) which refers to the online form for reporting adverse events, or by entering the link:

<https://sideeffects.health.gov.it>

6. Target Species:

Dogs

7. Amounts to be administered and administration route

For oral administration.

4 mg carprofen per kg bodyweight per day.

Do not exceed the stated dose

The tablets can be divided.

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 (No data available on the shelf life of the divided tablets)

8. How to use the preparation:

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 Carprofen Tablets at 4 mg/kg/day for up to 5 days.

9. Special warnings and precautions for use:

- Special precautions for use in Target 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.
 - Refer to: **Interaction with other medicinal products and other forms of interaction**
- Special precautions for the use in animals:
 - 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.
- 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.

- 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.
Do not use in bitches during estrus.
- 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.
Do not use concurrently with anti-coagulants.
Concurrent administration of potential nephrotoxic drugs should be avoided.

Overdose:

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.

10. Storage instructions

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.
- Storage conditions: Store below 25^oc. Store in a dry place. protect from light.
- Any halved tablets remaining after the last administration of the product must be discarded

11. Special precautions for the disposal of unused veterinary medicinal product 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 as toxic waste. Do not dispose of sewage.

12. FURTHER INFORMATION:

In addition to the active ingredient the product also contains:

- *Cellulose, microcrystalline*
- *Lactose monohydrate*
- *Croscarmellose sodium*
- *Povidone K30*
- *Sodium lauryl sulphate*
- *Magnesium stearate*
- *Tartrazine (E102) - in 100mg tablets only*

Pharmaceutical form:

Norocarp 20mg tablets: A white/off white circular tablet of diameter 8 mm, 20 embossed on one side and a single break line on the other side.

Norocarp 50mg tablets: A white/off white circular tablet of diameter 8 mm, 50 embossed on one side and a single break line on the other side.

Norocarp 100mg tablets: A yellow circular tablet of 8 mm diameter, 100 embossed on one side and a single breakline on the other side.

- Packaging size: Carton box with 10,20,30,50,60,70,100,140,180,200,250,280,300,500,1000 tablets divided in blisters, and carton box with 100 tablets in a bottle.
Not all pack sizes are marketed.

Registration holder: Comex Ltd, Nablus Rd. No.1, POB 19943, Jerusalem 97200

Manufacturer: Norbrook Laboratories Limited, Station Works, Newry, Northern Ireland, BT35 6JP, UK

Product registration number: 20 mg 083-53-92388-00

50 mg 083-52-92384-00

100 mg 154-02-33515-00

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