PACKAGE LEAFLET FOR:

Norocarp 20 mg tablets
Norocarp 50 mg tablets

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

Norocarp 20 mg tablets
Norocarp 50 mg tablets
carprofen

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

One tablet contains 20 mg or 50 mg carprofen

Other ingredients are: Microcrystalline cellulose, lactose monohydrate, crosscarmellose sodium, povidone K30, sodium lauril sulphate, magnesium stearate.

White/off white round tablet.

4. INDICATION(S)

Anti-inflammatory and analgesic treatment of disorders in muscles, joints and skeleton and the treatment of post surgical pain in dogs.

5. CONTRAINDICATIONS

Do not use for animals that are suffering from gastrointestinal disorders (including invasive GI tract surgery), haemostatic disorders, kidney disorders, moderate/severe liver or heart disorders or for animals showing signs of individual hypersensitivity to the product.
Do not use in cats.

6. ADVERSE REACTIONS

Undesirable effects of using NSAID-products include vomiting, diarrhoea, gastrointestinal bleeding, loss of appetite, lethargy and liver and kidney disorders. These effects are usually temporary but can in rare cases be serious and in few cases be lethal.

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

7. TARGET SPECIES

Dog.

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

For oral use.

The dose is 4 mg/kg bodyweight per day. The dose should be split and administered on two occasions in equal amounts. At treatment periods exceeding 14 days the dog should be regularly examined by a veterinary surgeon.

In order to prolong the anti-inflammatory and analgetic effect post operatively, parenteral treatment can be followed by peroral Norocarp Tablets at a dose of 4 mg per kg per day, split in two doses and administered on two occasions in equal amounts, for up to 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

This medicinal product does not require any special storage conditions.

12. SPECIAL WARNINGS

Caution is required when used to treat dogs less than 6 weeks of age, or very old dogs. Special precaution should be taken when medicating dehydrated, hypovolaemic animals or animals suffering from heart or liver diseases or infections. Simultaneous use of potent nephrotoxic drugs or other NSAIDs should be avoided.
Response to long term therapy should be monitored at regular intervals by a veterinary surgeon.

In the absence of specific studies in pregnant bitches, such use is not indicated. Carprofen passes to milk and should not be administered to lactating bitches.

Carprofen should not be administered simultaneous to or within 24 hrs of administration with other NSAIDs or steroids or together with anticoagulants. Carprofen is highly protein bound and may therefore compete with other highly protein bound drugs.

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

Not applicable.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

2019-05-03

15. OTHER INFORMATION

Tablet container of polypropylene sealed with a polyethylene cap
20 mg: 100 and 500 tablets.
50 mg: 100 and 500 tablets.

Blister of PVC/aluminium:
20 mg: 10, 20 and 100 tablets.
50 mg: 10, 20, 100 and 500 tablets.

Not all pack sizes may be marketed.