A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CARPRODYL F 20 mg, tablets for dogs.
Carprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains: carprofen 20 mg & yellow iron oxide

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

20 tablets
100 tablets
200 tablets
500 tablets

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet for storage conditions

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before disposal

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

XXXX

16. MARKETING AUTHORISATION NUMBER(S)

XXXX

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters of 10 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CARPRODYL F 20 mg, tablets.
Carprofen

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

CARPRODYL F 20 mg, tablets for dogs. [AT BE CY DE DK EL FR HU IE IT LU NL PT PL SK UK]
CARPRODYL F 50 mg, tablets for dogs. [AT BE CY DE DK EL FR HU IE IT LU NL PT PL SK UK]
CARPRODYL F 100 mg, tablets for dogs[AT BE CY DE DK EL FR HU IE IT LU NL PT PL SK UK]

CARPRODYL 20 mg, tablets for dogs [ES SE]
CARPRODYL 50 mg, tablets for dogs [ES SE]
CARPRODYL 100 mg, tablets for dogs [ES SE]

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

Marketing authorisation holder:
xxxx

Manufacturer for the batch release:
CEVA SANTE ANIMALE - Z.I. Très le Bois - 22600 Loudéac - FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CARPRODYL F 20 mg, tablets for dogs.
CARPRODYL F 50 mg, tablets for dogs.
CARPRODYL F 100 mg, tablets for dogs.
Carprofen

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

Each tablet contains:
CARPRODYL F 20 mg carprofen 20 mg & yellow iron oxide 0.0375 mg (E 172)
CARPRODYL F 50 mg carprofen 50 mg & yellow iron oxide 0.09375mg (E 172)
CARPRODYL F 100 mg carprofen 100 mg & yellow iron oxide 0.1875 mg (E 172)
Circular beige scored tablets.
The tablets can be divided into equal halves.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in cats.
Do not use in pregnant or lactating bitches.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients of the product.
Do not use in dogs suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding, or where there is evidence of a blood dyscrasia.
Do not use in pups less than 4 months of age.

6. ADVERSE REACTIONS

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.
Rare cases of gastrointestinal bleeding are reported.
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 rare risk of renal or idiosyncratic hepatic adverse events.
If you notice any serious effects or others effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

For oral administration.
4 mg carprofen per kg bodyweight per day
To limit the inflammation and relieve the pain caused by musculo-skeletal disorders and degenerative joint disease:
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose or in two equally divided doses. The daily dose may be reduced, subject to clinical response.
Duration of treatment will be dependant upon the response seen. Long term treatment should be under regular veterinary supervision.
To extend analgesic and anti-inflammatory cover post-operatively, parenteral preoperative treatment with carprofen injection may be followed with carprofen tablets at 4mg/kg/day for 5 days.
Do not exceed the stated dose.
The tablets are flavoured and consequently taken by most of dogs voluntarily.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

This medicinal product does not require any special temperature storage conditions
Store tablets and half-tablets in the original blister in order to protect from light.
Halved tablets should be used within 7 days.
Do not use after the expiry date which is stated on the carton and blister after “EXP”.
Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Use in aged dogs may involve additional risk. If such a use cannot be avoided, dogs may require 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.
Response to long term treatment should be monitored at regular intervals by a veterinary surgeon.
As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

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

Pregnancy and lactation
Studies in laboratory species (rat and rabbit) have shown evidence of foetotoxic effects of carprofen at doses close to the therapeutic dose.
In dogs, the safety of the veterinary medicinal product has not been investigated during pregnancy and lactation. Do not use in pregnant or lactating bitches.

Interactions
Carprofen must not be administered with glucocorticoids.
Do not administer other NSAIDs 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.

Overdose
No signs of toxicity appeared when dogs were treated with carprofen at levels up to 6 mg/kg twice daily for 7 days (3 times the recommended dose rate of 4 mg/kg) and 6 mg/kg once daily for a further 7 days (1.5 times the recommended dose rate of 4 mg/kg).
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs, should be applied.
Contact your veterinarian immediately if your dog eats more than the prescribed amount of CARPRODYL F.
Severe adverse reactions may occur if large quantities are ingested. If you suspect that your dog has consumed tablets above the labelled dose, contact your veterinarian.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

CARPRODYL F tablets are flavoured and consequently taken by most of dogs voluntarily.

Pack sizes:

Carprodyl F 20 mg:
Box containing 20 tablets: 2 blisters of 10 tablets
Box containing 100 tablets: 10 blisters of 10 tablets
Box containing 200 tablets: 20 blisters of 10 tablets
Box containing 500 tablets: 50 blisters of 10 tablets

Carprodyl F 50 & 100 mg:
Box containing 20 tablets: 4 blisters of 5 tablets
Box containing 100 tablets: 20 blisters of 5 tablets
Box containing 200 tablets: 40 blisters of 5 tablets
Box containing 500 tablets: 100 blisters of 5 tablets

Not all pack sizes may be marketed.