<PARTICULARS TO APPEAR ON THE OUTER PACKAGE > < PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimifin 100mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Active Ingredient
One Grilled meat flavoured tablet contains:
Carprofen 100.0 mg/tablet

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

Containers:
6, 10, 14, 20, 28, 30, 42, 50, 60, 70, 84, 98, 100, 140, 180, 200, 250, 280 and 300 tablets

Blisters:
6, 10, 14, 20, 28, 30, 42, 50, 56, 60, 70, 84, 98, 100, 140, 180, 200, 250, 280, 300, 500 and 1000 tablets

5. TARGET SPECIES

Dogs

6. 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 following soft tissue surgery.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

The tablets can be divided into halves or quarters.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Store in a dry place in the original package. Protect from light.
Return any divided tablets to the blister pack or container and use within 72 hours.
Divided tablets should be used at the next administration.

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

Disposal: Read the package leaflet.

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 sight and reach of children.

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

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

16. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

Vm 08749/4008

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimifin 100mg tablets for dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

Package leaflet
RIMIFIN 100mg TABLETS FOR DOGS
CARPROFEN

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

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rimifin 100mg tablets for dogs

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

One Grilled Meat Flavoured tablet contains:
Carprofen 100.0 mg/tablet
A white to off white round shape tablets with cross break line on one side.
The tablets can be divided into halves or quarters.

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 following soft tissue surgery.

5. CONTRAINDICATIONS

Do not use in cats.
Do not use in case of hypersensitivity to 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 gastro-intestinal 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/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.
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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

For oral administration.
4 mg carprofen per kg bodyweight per day.
An initial dose of 4 mg carprofen per kg bodyweight per day given as a single daily dose or in two equally divided doses may, subject to clinical response, be reduced after 7 days to 2 mg carprofen/kg bodyweight/day given as a single dose.
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 may be followed with Carprofen tablets at 4mg/kg/day for 2 days.
Do not exceed the stated dose.

9. ADVICE ON CORRECT ADMINISTRATION

Return any divided tablets to the blister pack or container and use within 72 hours. Divided tablets should be used at the next administration. Any divided tablets remaining after the last administration of the product should be discarded.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Store in a dry place in the original package. Protect from light.
Do not use after the expiry date stated on the label.

Return any divided tablets to the blister pack or container and use within 72 hours.
Divided tablets should be used at the next administration.

12. SPECIAL WARNINGS

Do not use in pregnant or lactating bitches.
Use in dogs less than 6 weeks of age, or 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, hypovolaemic or hypotensive dog, as there is a potential risk of increased renal toxicity.
Concurrent administration of potential nephrotoxic drugs should be avoided.

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 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.
Carprofen must not be administered with glucocorticoids.
There is no specific antidote for carprofen overdosage but general supportive therapy, as applied to clinical overdosage with NSAIDs should be applied.
Special precautions to be taken by the person administering the 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.

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

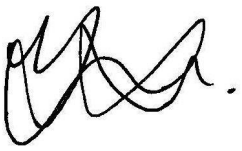
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

15. OTHER INFORMATION

Pack sizes for blisters
6, 10, 14, 20, 28, 30, 42, 50, 56, 60, 70, 84, 98, 100, 140, 180, 200, 250, 280, 300, 500, 1000 tablets.
Pack sizes for containers:
100mg: 6, 10, 14, 20, 28, 30, 42, 50, 60, 70, 84, 98, 100, 140, 180, 200, 250, 280, 300
Not all pack sizes may be marketed.
For animal treatment only.



Approved: 28 November 2019