Product name: ONSIOR 20 mg Tablets for Dogs
APVMA No. 63107
ACVM: A10706
Date: 30 October 2013

Text above this line is not included

Blister (international)

ONSIOR
20 mg robenacoxib

Tablets for dogs
For animal treatment only

NOVARTIS LOGO

EXP
LOT

DISPLAYED BY INFOPEST

APVMA
RLP
Approved

Product name: ONSIOR 20 mg Tablets for Dogs
APVMA No. 63107
ACVM: A10706
Date: 30 October 2013

Text above this line is not included

Carton – front panel

PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS BEFORE OPENING OR USING
FOR ANIMAL TREATMENT ONLY

ONSIOR® 20 mg Tablets for Dogs

Each tablet contains 20 mg robenacoxib

For the control of pain and inflammation associated with chronic osteoarthritis or orthopaedic or soft tissue surgery in dogs.

7 tablets [28 tablets]

NOVARTIS LOGO

Product name: ONSIOR 20 mg Tablets for Dogs
APVMA No. 63107
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Carton – back panel

READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT

DIRECTIONS FOR USE

ONSIOR Tablets should be given on an empty stomach or with only a small amount of food. The recommended dose rate and regime should not be exceeded.

For control of pain and inflammation associated with chronic osteoarthritis
Administer orally once per day at a dose of 1 mg/kg bodyweight with a range of 1-2 mg/kg.

For control of pain and inflammation associated with orthopaedic or soft tissue surgery
Initiate treatment with a SINGLE dose of ONSIOR Injection administered subcutaneously before commencement of surgery, for example around the time of induction of general anaesthesia or initiation of supportive fluid therapy, at a dose of 2 mg/kg (1 mL per 10 kg bodyweight). If treatment is to be continued, ONSIOR Tablets may be administered orally at 1 mg/kg bodyweight, dose range 1-2 mg/kg, ONCE daily for up to 12 days.

The enclosed leaflet describes directions for use and precautions to follow when administering ONSIOR Tablets.

Safety Directions
May irritate the eyes. Avoid contact with eyes. Wash hands after use.

First Aid
If poisoning occurs, contact a doctor or Poisons Information Centre. *Phone Australia 13 1126.*

Storage
Store below 25°C (Air Conditioning).

Disposal
Dispose of empty containers by wrapping in paper and putting in garbage.

Product name: ONSIOR 20 mg Tablets for Dogs
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Date: 30 October 2013

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Australia
NOVARTIS Animal Health Australasia Pty Limited,
ACN 076 745 198
54 Waterloo Road
North Ryde NSW 2113

APVMA Approval No. 63107/59317

[B]
EXP

Product name: ONSIOR 20 mg Tablets for Dogs
APVMA No. 63107
ACVM: AI0706
Date: 30 October 2013

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PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
READ SAFETY DIRECTIONS BEFORE OPENING OR USING
FOR ANIMAL TREATMENT ONLY

ONSIOR® 5 mg Tablets for Dogs
(Each tablet contains 5 mg ROBENACOXIB)

ONSIOR® 10 mg Tablets for Dogs
(Each tablet contains 10 mg ROBENACOXIB)

ONSIOR® 20 mg Tablets for Dogs
(Each tablet contains 20 mg ROBENACOXIB)

ONSIOR® 40 mg Tablets for Dogs
(Each tablet contains 40 mg ROBENACOXIB)

INDICATIONS
For the control of pain and inflammation associated with chronic osteoarthritis or orthopaedic or soft tissue surgery in dogs.

INTRODUCTION
ONSIOR Tablets contain robenacoxib, a cyclooxygenase-2 (COX-2) selective non-steroidal anti-inflammatory drug (NSAID) of the coxib class.

DIRECTIONS FOR USE

CONTRAINDICATIONS
Contraindicated for use in animals suffering from gastrointestinal ulceration.
Contraindicated for use concomitantly with corticosteroids or other NSAIDs.
Contraindicated for use in dogs with known hypersensitivity to robenacoxib.
Contraindicated for use in cats. For cats use ONSIOR 6 mg Tablets for Cats.

PRECAUTIONS
The safety of ONSIOR Tablets in dogs weighing less than 2.5 kg, dogs younger than three months of age, or in breeding, pregnant or lactating dogs has not been established.

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Additional risk may be involved with the use of ONSIOR in dogs with impaired function of the heart, kidney or liver, or that are dehydrated, have low circulating blood volume or low blood pressure. If use cannot be avoided, these dogs require careful monitoring.
Use ONSIOR under strict veterinary monitoring in dogs at risk of gastrointestinal ulceration or if the dog previously displayed intolerance to other NSAIDs.

ONSIOR should not be given to animals with impaired hydration status, cardiac or renal insufficiency or where subsequent blood loss or decrease in blood pressure during surgery may decrease renal or gut perfusion. Supportive fluid therapy is therefore recommended during surgery.

Prior to administration of any NSAID it is advisable to conduct a physical examination and appropriate laboratory tests (including liver enzymes) to establish pre-treatment parameters. During prolonged therapy, appropriate re-evaluation and monitoring of body function tests should be undertaken periodically as deemed appropriate for the individual patient. The dose for prolonged therapy in dogs should be as near to the bottom of the dose range as is compatible with clinical response. ONSIOR has been used in dogs for up to 12 months. Therapy should be discontinued if liver enzymes increase markedly or the dog shows clinical signs such as anorexia, apathy or vomiting in combination with elevated liver enzymes.

ONSIOR must not be administered in conjunction with other NSAIDs. Pre-treatment with other anti-inflammatory medicines may result in additional or increased adverse effects and, accordingly a treatment-free period with such substances should be observed for at least 24 hours before the commencement of treatment with ONSIOR. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Concomitant treatment with medicines displaying action on renal flow, e.g. diuretics or angiotensin converting enzyme (ACE) inhibitors, should be subject to clinical monitoring.

Concurrent administration of potentially nephrotoxic substances should be avoided as there might be an increased risk of renal toxicity.
Concurrent use of other active substances that have a high degree of protein binding may compete with robenacoxib for binding and thus lead to toxic effects.

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DOSAGE AND ADMINISTRATION

ONSIOR Tablets should be given on an empty stomach or with only a small amount of food. ONSIOR Tablets are flavoured and are taken voluntarily by most dogs.
If a dose is missed, it should be administered as soon as remembered, and the following dose given the next day at the usual dosing time.
The recommended dose rate and regime should not be exceeded.
Tablets should not be divided or broken.

Osteoarthritis
Administer orally once per day at a dosage of 1 mg/kg bodyweight with a range of 1-2 mg/kg.
For long-term treatment, once clinical response has been observed, the dose of ONSIOR can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic arthritis can vary over time. Regular monitoring should be undertaken by the veterinarian.

Bodyweight (kg)	**Number of tablets by size**			
	5 mg	**10 mg**	**20 mg**	**40 mg**
2.5 – <5	1 tablet			
5 – <10		1 tablet		
10 - <20			1 tablet	
20 - <40				1 tablet
40 – 80				2 tablets

Soft tissue or orthopaedic surgery
Initiate treatment with a SINGLE dose of ONSIOR INJECTION administered subcutaneously before commencement of surgery, for example around the time of induction of general anaesthesia or initiation of supportive fluid therapy, at a dose of 2 mg/kg (1 mL per 10 kg bodyweight). If treatment is to be continued, ONSIOR tablets may be administered orally at 1 mg/kg bodyweight, dose range 1-2 mg/kg, ONCE daily for up to 12 days.

SIDE EFFECTS

Robenacoxib is an NSAID, and as with other such drugs, adverse reactions may occur. Typical adverse reactions observed in clinical trials include mild and transient diarrhoea, soft to watery faeces, and vomiting.
Increases in liver enzymes may be seen in dogs after long-term treatment.

TOLERABILITY

Tolerability studies have been conducted with ONSIOR Tablets for periods ranging from 4 weeks to 6 months, and robenacoxib was well tolerated in dogs at

Text above this line is not included

recommended daily dosing rates or with substantial overdose (40 mg/kg daily for 4 weeks, 10 mg/kg daily for 6 months).

ONSIOR Tablets have been used during clinical trials in conjunction with other common medications, including anthelmintics, flea control medications, anaesthetics, pre-anaesthetic medications, vaccinations and antibiotics. While the safety of concomitant use of ONSIOR Tablets with each of these medications was not specifically evaluated, there were no apparent changes in the adverse event profile when ONSIOR was given with these other medications.

SAFETY DIRECTIONS

May irritate the eyes. Avoid contact with eyes. Wash hands after use.

FIRST AID

If poisoning occurs, contact a doctor or Poisons Information Centre.
Phone Australia 13 1126.

STORAGE

Store below 25°C (Air Conditioning).

DISPOSAL

Dispose of empty containers by wrapping in paper and putting in garbage.

WARRANTY AND EXCLUSION OF LIABILITY:

This product is warranted fit for the purposes specifically recommended by Novartis Animal Health Australasia Pty Ltd when used strictly as directed in this leaflet. All other warranties and obligations or liabilities, whether expressed or implied by statute or otherwise, are excluded to the full extent that exclusion is permitted by law.

AUSTRALIA NOVARTIS CUSTOMER ASSISTANCE

☎ 1800 633 768 TOLL FREE from anywhere in Australia
8.30 am to 5.30 pm E.S.T. Monday to Friday

Australia
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ACN 076 745 198
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APVMA Approval Nos. 63104/59315, 63105/59316, 63107/59317, 63109/59318