

# Onsior<sup>®</sup> Dog Package Leaflet

## PACKAGE LEAFLET FOR:

**Onsior 5 mg tablets for dogs**  
**Onsior 10 mg tablets for dogs**  
**Onsior 20 mg tablets for dogs**  
**Onsior 40 mg tablets for dogs**

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

### Marketing authorisation holder

Novartis Animal Health UK Ltd  
Frimley Business Park  
Frimley/Camberley  
Surrey, GU16 7SR  
United Kingdom

### Manufacturer for the batch release:

Novartis Santé Animale S.A.S.  
26 Rue de la Chapelle  
F-68330 Huningue  
France

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Onsior 5 mg tablets for dogs  
Onsior 10 mg tablets for dogs  
Onsior 20 mg tablets for dogs  
Onsior 40 mg tablets for dogs  
Robenacoxib

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

Each tablet contains the following amount of robenacoxib and bears the imprint "NA" on one side and the following imprint on the other side:

Robenacoxib/tablet	Imprint
5 mg	AK
10 mg	BE
20 mg	CD
40 mg	BCK

Tablets are round, beige to brown and non-divisible. Onsior tablets are flavoured and are taken voluntarily by most dogs.

### 4. INDICATION(S)

For the treatment of pain and inflammation of chronic osteoarthritis in dogs.

### 5. CONTRAINDICATIONS

Do not use in dogs suffering from stomach ulcer or with liver disease.

Do not use together with other non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids, medicines commonly used in the treatment of pain, inflammation and allergies.

Do not use in case of hypersensitivity to robenacoxib or to any of the ingredients of the tablets.

Do not use in pregnant or lactating bitches because the safety of robenacoxib has not been established during pregnancy and lactation or in dogs used for breeding.

### 6. ADVERSE REACTIONS\*

Adverse reactions of the digestive tract were reported very commonly, but most cases were mild and recovered without treatment. Vomiting and soft faeces were very common, decreased appetite and diarrhoea were common, and blood in the faeces was uncommon.

In dogs treated up to 2 weeks no increases in liver enzyme activities were observed. However, with long-term treatment increases in liver enzyme activities were common. In most cases the liver enzyme activities either stabilised or decreased with continued treatment. Increases in liver enzyme activities associated with symptoms of anorexia, apathy or vomiting were uncommon.

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

\* The frequency of possible adverse effects is defined using the following convention:

very common (affects more than 1 animal in 10)

common (affects 1 to 10 animals in 100)

uncommon (affects 1 to 10 animals in 1,000)

rare (affects 1 to 10 animals in 10,000)

very rare (affects less than 1 animals in 10,000)

not known (frequency cannot be estimated from the available data).

## 7. TARGET SPECIES

Dog

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

The recommended dose of robenacoxib is 1 mg/kg body weight with a range 1-2 mg/kg. Administer once daily at the same time every day according to the table below.

Body weight (kg)	Number of tablets			
	5 mg	10 mg	20 mg	40 mg
2.5 to < 5	1 tablet			
5 to < 10		1 tablet		
10 to < 20			1 tablet	
20 to < 40				1 tablet
40 to 80				2 tablets

A clinical response is normally seen within a week. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

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 osteoarthritis may vary over time. Regular monitoring should be undertaken by the veterinarian.

## 9. ADVICE ON CORRECT ADMINISTRATION

Give orally. Do not administer with food since clinical trials demonstrated better efficacy of robenacoxib when administered without food or at least 30 minutes before or after a meal. Onsior tablets are flavoured and are taken voluntarily by most dogs. The tablets should not be divided or broken.

## 10. WITHDRAWAL PERIOD

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children. Store below 25°C. Do not use after the expiry date stated on the blister after EXP.

## 12. SPECIAL WARNING(S)

The safety of this veterinary medicinal product has not been established in dogs weighing less than 2.5 kg or under 3 months of age.

For long term therapy, liver enzymes should be monitored at the start of therapy, e.g. after 2, 4 and 8 weeks. Thereafter it is recommended to continue regular monitoring, e.g. every 3-6 months. Therapy should be discontinued if liver enzyme activities increase markedly or the dog shows symptoms such as anorexia, apathy or vomiting in combination with elevated liver enzymes.

Use in dogs with impaired function of the heart, kidneys or liver or in dogs that are dehydrated, have low volume of circulating blood or have low blood pressure may involve additional risk. If use cannot be avoided, these dogs require careful monitoring.

Use this veterinary medicinal product under strict veterinary monitoring in dogs at risk of stomach ulcer or if the animal previously displayed intolerance to other NSAIDs.

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 medicines 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.

#### **For the person administering the veterinary medicinal product to animals**

Wash hands after use of the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. In small children, accidental ingestion increases the risk for NSAID adverse effects.

For pregnant women, particularly near term pregnant women, prolonged dermal exposure might increase the risk to the foetus.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

06/2009

Detailed information on this product is available on the website of the European Medicines Agency (EMA) <http://www.emea.europa.eu/>.

### **15. OTHER INFORMATION**

Onsior tablets for dogs are available in cardboard boxes containing 1, 2, 4 or 10 blisters. Each blister contains 7 tablets. Not all pack sizes may be marketed.

Robenacoxib is a non-steroidal anti-inflammatory drug (NSAID). It selectively inhibits the cyclooxygenase 2 enzyme (COX-2), which is responsible for pain, inflammation or fever. The cyclooxygenase 1 enzyme (COX-1) which has protective functions, e.g. in the digestive tract and kidneys, is not inhibited by robenacoxib.

In artificially induced inflammation in dogs, robenacoxib reduced pain and inflammation with single oral doses ranging from 0.5 to 8 mg/kg and a rapid onset of action (0.5 h). This product reduced in clinical trials the lameness and inflammation of dogs with chronic osteoarthritis.