PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Onsior 10 mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

10 mg robenacoxib/tablet

3. PACKAGE SIZE

7 tablets
14 tablets
28 tablets
70 tablets
30 x 1 tablets
60 x 1 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Keep the tablet blisters in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5019

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V - To be supplied only on veterinary prescription

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Blister Foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Onsior

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Robenacoxib 10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco (logo)

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Onsior 10 mg tablets for dogs

2. COMPOSITION

Each tablet contains:

Robenacoxib	Imprints
5 mg	AK
10 mg	BE
20 mg	CD
40 mg	BCK

Round, beige to brown and non-divisible tablets with the imprint “NA” on one side and the upper-mentioned imprint on the other side.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

For the treatment of pain and inflammation of chronic osteoarthritis in dogs.
For the treatment of pain and inflammation associated with soft tissue surgery 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. SPECIAL WARNING(S)

Special warnings:

In clinical studies in dogs with osteoarthritis, inadequate response to treatment was seen in 10–15% of the dogs.

Special precautions for safe use in the target species:

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.

Special precautions to be taken by 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.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Fertility:

The safety of the veterinary medicinal product has not been established in dogs used for breeding.

Interaction with other medicinal products and other forms of interaction:

This veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticoids. 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 this veterinary medicinal product . 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. In healthy dogs treated with and without the diuretic furosemide, concomitant administration of this veterinary medicinal product with the ACE inhibitor benazepril for 7 days was not associated with any negative effects on urine aldosterone concentrations, plasma renin activity or glomerular filtration rate. No safety data in the target population and no efficacy data in general exist for the combined treatment of robenacoxib and benazepril.

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.

Overdose

In healthy young dogs aged 5–6 months, oral robenacoxib administered at high overdoses (4, 6 or 10 mg/kg/day for 6 months) did not produce any signs of toxicity, including no evidence of any gastrointestinal, kidney or liver toxicity and no effect on bleeding time. Robenacoxib also had no detrimental effects on cartilages or joints.
As with any NSAID, overdose may cause gastrointestinal, kidney, or liver toxicity in sensitive or compromised dogs. There is no specific antidote. Symptomatic, supportive therapy is recommended consisting of administration of gastrointestinal protective agents and infusion of isotonic saline.

The interchangeable use of Onsior tablets and Onsior solution for injection in mongrel dogs at overdoses of up to 3 times the maximum recommended dose (2.0, 4.0 and 6.0 plus 4.0, 8.0 and 12.0 mg robenacoxib/kg orally and 2.0 mg, 4.0 mg and 6.0 mg robenacoxib/kg subcutaneously) resulted in dose-related oedema, erythema, thickening of the skin and skin ulceration at the subcutaneous injection site and inflammation, congestion or haemorrhage in the duodenum, jejunum and caecum. No relevant effects on body weight, bleeding time or evidence of any kidney or liver toxicity were observed.

7. ADVERSE EVENTS

Dogs:

Very common (>1 animal / 10 animals treated):	Digestive tract disorder[1], Diarrhoea, Vomiting
Common (1 to 10 animals / 100 animals treated):	Elevated liver enzymes[2] Decreased appetite
Uncommon (1 to 10 animals / 1,000 animals treated):	Blood in the faeces
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Lethargy

[1]Most cases were mild and recovered without treatment.
[2]In dogs treated up to 2 weeks, there were no increases in liver enzyme activities observed. However, with long-term treatment, increases in liver enzyme activities were reported. In most cases there were no clinical signs and the liver enzyme activities either stabilised or decreased with continued treatment. Increases in liver enzyme activities associated with clinical signs of anorexia, apathy or vomiting were uncommon.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

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

For oral use.

Osteoarthritis: 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.

Number of Tablets by Strength and Body Weight for Osteoarthritis

Body Weight (kg)	Number of Tablets by Strength			
	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 a clinical response has been observed, the dose of this veterinary medicinal product 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**.**

Soft tissue surgery: The recommended dose of robenacoxib is 2 mg/kg body weight with a range of 2-4 mg/kg. Give as a single oral treatment prior to soft tissue surgery.
The tablet(s) should be administered without food at least 30 minutes prior to surgery.

After surgery, once daily treatment may be continued for up to two further days.

Number of tablets by strength and body weight for soft tissue surgery

Body Weight (kg)	Number of Tablets by Strength			
	5 mg	**10 mg**	**20 mg**	**40 mg**
2.5	1 tablet			
> 2.5 to < 5		1 tablet		
5 to < 10			1 tablet	

10 to < 20				1 tablet
20 to < 40				2 tablets
40 to < 60				3 tablets
60 to 80				4 tablets

The interchangeable use of Onsior tablets and Onsior solution for injection has been tested in a target animal safety study and was shown to be well tolerated by dogs.

For dogs, Onsior solution for injection or tablets may be used interchangeably in accordance with the indications and directions of use approved for each pharmaceutical form. Treatment should not exceed one dose (either tablet or injection) per day. Please note that the recommended doses for the two formulations may be different.

9. ADVICE ON CORRECT ADMINISTRATION

Do not administer with food since clinical trials demonstrated better efficacy of robenacoxib for osteoarthritis when administered without food or at least 30 minutes before or after a meal. Soft Tissue Surgery: Administer the first dose at least 30 minutes prior to surgery. The tablets are flavoured and are taken voluntarily by most dogs. The tablets should not be divided or broken.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Store below 25 °C. Do not use this veterinary medicinal product after the expiry date which is stated on the carton or blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5019

Cardboard boxes containing 7, 14, 28 or 70 tablets in Alu/Alu blisters, 30 x 1 tablets or 60 x 1 tablets in Alu/Alu perforated unit dose blisters. Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH,Heinz-Lohmann Strasse 4,Groden,D-27472 Cuxhaven,Germany

PV.GBR@elancoah.com

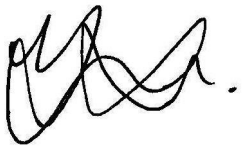
Manufacturer responsible for batch release:

Elanco France S.A.S., 26 Rue de la Chapelle, 68330 Huningue, France

17. OTHER INFORMATION

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). In clinical trials this product reduced the lameness and inflammation of dogs with chronic osteoarthritis and pain, inflammation and the need for rescue treatment in dogs undergoing soft tissue surgery.



Approved: 12 October 2023