PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Onsior 6 mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

6 mg robenacoxib/tablet

3. PACKAGE SIZE

6 x 1 tablets
12 x 1 tablets
30 x 1 tablets
60 x 1 tablets

4. TARGET SPECIES

Cats.

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 NUMBER

Vm 52127/5024

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 6mg**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 6 mg tablets for cats

2. COMPOSITION

Each tablet contains 6 mg robenacoxib.
Round, beige to brown, non-divisible tablets with imprints “NA” on one side and “AK” on the other side.

3. TARGET SPECIES

Cats.

4. INDICATIONS FOR USE

For the treatment of pain and inflammation associated with acute and chronic musculoskeletal disorders in cats.
For the reduction of moderate pain and inflammation associated with orthopaedic surgery in cats.

5. CONTRAINDICATIONS

Do not use in cats suffering from ulceration in the digestive tract.
Do not use together with 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 constituents of the tablets.
Do not use in pregnant or lactating cats or cats used for breeding because the safety of this product has not been established in these animals.

6. SPECIAL WARNING(S)

Special precautions for safe use in the target species:
The safety of this veterinary medicinal product has not been established in cats weighing less than 2.5 kg or under 4 months of age.

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

Response to long-term treatment should be monitored at regular intervals by a veterinary surgeon. Clinical field studies showed that robenacoxib was well-tolerated by most cats for up to 12 weeks.
Use this veterinary medicinal product under strict veterinary monitoring in cats 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 may 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 cats 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 glucocorticosteroids. Pre-treatment with other anti-inflammatory medicines may result in additional or increased adverse effects and 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 cats treated with or 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 plasma 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.

As anaesthetics may affect renal perfusion, the use of parenteral fluid therapy during surgery should be considered to decrease potential renal complications when using NSAIDs peri-operatively.

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 cats aged 7–8 months, oral robenacoxib administered at high overdoses (4, 12 or 20 mg/kg/day for 6 weeks) did not produce any signs of toxicity, including no evidence of any gastrointestinal, kidney or liver toxicity and no effect on bleeding time.

In healthy young cats aged 7- 8 months, oral robenacoxib administered at overdoses of up to 5 times the maximum recommended dose (2.4 mg, 7.2 mg, 12 mg robenacoxib/kg bodyweight) for 6 months was well tolerated. A reduction in body weight gain was observed in treated animals. In the high dose group kidney weights were decreased and sporadically associated with renal tubular degeneration/ regeneration but not correlated with evidence of renal dysfunction on clinical pathology parameters.

The interchangeable use of Onsior tablets and Onsior solution for injection in 4-month old cats at overdoses of up to 3 times the maximum recommended dose (2.4 mg, 4.8 mg, 7.2 mg robenacoxib/kg orally and 2.0 mg, 4.0 mg and 6.0 mg robenacoxib/kg subcutaneously) resulted in a dose-dependent increase of sporadic oedema at the injection site and minimal to mild subacute/chronic inflammation of the subcutaneous tissue. A dose-dependent increase in the QT interval, a decreased heart rate and corresponding increased respiratory rate were observed in laboratory studies. No relevant effects on body weight, bleeding time or evidence of any gastrointestinal, kidney or liver toxicity were observed.

In overdose studies conducted in cats, there was a dose-dependent increase in the QT interval. The biological relevance of increased QT intervals outside of normal variations observed following overdose of robenacoxib is unknown. No changes in the QT interval were observed after a single intravenous administration of 2 or 4 mg/kg robenacoxib to anaesthetised healthy cats.

As with any NSAID, overdose may cause gastrointestinal, kidney, or liver toxicity in sensitive or compromised cats. There is no specific antidote. Symptomatic, supportive therapy is recommended and should consist of administration of gastrointestinal protective agents and infusion of isotonic saline.

7. ADVERSE EVENTS

Cats:

Common (1 to 10 animals / 100 animals treated):	Diarrhoea[1], Vomiting[1]
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Elevated renal parameters (creatinine, BUN, and SDMA)[2] Renal insufficiency[2] Lethargy

[1] Mild and transient
[2] More commonly in older cats with concomitant use of anaesthetic or sedative agents.

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.
The recommended dose of robenacoxib is 1 mg/kg body weight with a range 1–2.4 mg/kg. The following number of tablets should be given once daily at the same time every day.

Body weight (kg)	Number of tablets
2.5 to < 6	1 tablet
6 to 12	2 tablets

Acute musculoskeletal disorders: treat for up to 6 days.

Chronic musculoskeletal disorders: Duration of treatment should be decided on an individual basis.

A clinical response is normally seen within 3-6 weeks. Treatment should be discontinued after 6 weeks if no clinical improvement is apparent.

Orthopaedic surgery: Give as a single oral treatment prior to orthopaedic surgery. Premedication should only be carried out in combination with butorphanol-analgesia. 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. If necessary, additional analgesic treatment with opioids is recommended.

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 the cats.

For cats, Onsior solution for injection or tablets may be used interchangeably in accordance with the indications and duration 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 are different.

9. ADVICE ON CORRECT ADMINISTRATION

Give either without food or with a small amount of food. The tablets are easy to administer and well accepted by most cats. 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 product 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 52127/5024

Cardboard boxes containing 6 x 1, 12 x 1, 30 x 1 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

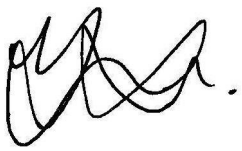
PV.GBR@elancoah.com

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 clinical trials in cats this product reduced pain and inflammation associated with acute musculoskeletal disorders and reduced the need for rescue treatment when given as premedication in case of orthopaedic surgery, in combination with opioids. In two clinical trials in (mainly indoor) cats with chronic musculoskeletal disorder (CMSD), robenacoxib increased the activity and improved subjective scores of activity, behaviour, quality of life, temperament and happiness of the cats. Differences between robenacoxib and placebo were significant ($P<0.05$) for the client specific outcome measures, but did not reach significance ($P=0.07$) for the feline musculoskeletal pain index.

In a clinical study, 10 of 35 CMSD cats were assessed to be significantly more active when treated with robenacoxib for three weeks compared to these same cats when they received a placebo treatment. Two cats were more active when given placebo and for the remaining 23 cats no significant difference in activity could be detected between robenacoxib and placebo treatment.



Approved: 12 October 2023