PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Onsior 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

20 mg/ml robenacoxib

Sodium metabisulphite (E 223)

3. PACKAGE SIZE

20 ml

4. TARGET SPECIES

Cats and Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days
Once broached, use by…….

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C). Keep the vial in the outer carton.
Refrigeration is not required during the 4-week in-use period after first broaching of the vial.

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 52127/5021

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 SMALL IMMEDIATE PACKAGING UNITS Glass Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Onsior

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

20 mg/ml robenacoxib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use by…

Once broached use within 28 days.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIOD

8. 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 20 mg/ml solution for injection for cats and dogs

2. COMPOSITION

Each ml contains 20 mg robenacoxib as active substance and 1 mg sodium metabisulphite (E 223) as an antioxidant.
Clear, colourless to slightly coloured (pink) liquid.

3. TARGET SPECIES

Cats and dogs.

4. INDICATIONS FOR USE

For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in dogs.
For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in cats.

5. CONTRAINDICATIONS

Do not use in animals suffering from gastrointestinal ulceration.
Do not use together with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).
Do not use in case of hypersensitivity to robenacoxib or to any ingredients of the solution.
Do not use in pregnant or lactating animals because the safety of robenacoxib has not been established during pregnancy and lactation or in cats and dogs used for breeding.

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 less than 4 months of age and in dogs less than 2 months of age, or in cats or dogs less than 2.5 kg body weight.

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

Use this veterinary medicinal product under strict veterinary monitoring in animals at risk of ulceration of the digestive tract, 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 and exposed skin immediately after use of the veterinary medicinal product.

In case of accidental ingestion or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

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 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 cats or dogs 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 (cats) or urine (dogs) 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.

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 and dogs used for breeding.

Overdose

In healthy young dogs aged 6 months, once daily subcutaneous administration of robenacoxib at doses of 2 (recommended therapeutic dose; RTD), 6 (3 times RTD), and 20 mg/kg (10 times RTD) for 9 administrations over a 5 week period (3 cycles of 3 consecutive once daily injections) did not produce any signs of toxicity, including gastrointestinal, kidney or liver toxicity and had no effect on bleeding time. Reversible inflammation at the injection site was noted in all groups (including controls) and was more severe in the 6 and 20 mg/kg dose groups.

In healthy young cats aged 10 months, once daily subcutaneous administration of robenacoxib at doses of 4 mg/kg (twice RTD) for 2 consecutive days and 10 mg/kg (5 times RTD) for 3 consecutive days did not produce any signs of toxicity, including signs of gastrointestinal, kidney or liver toxicity and had no effect on bleeding time. Reversible, minimal injection site reactions were noted in both dose groups.

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.

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.

No changes to blood pressure or the electrocardiogram were observed after single administration to healthy dogs of 2 mg/kg robenacoxib subcutaneously or 2 or 4 mg/kg intravenously. Vomiting occurred 6 or 8 hours post-dosing in 2 of 8 dogs administered the solution for injection at a dosage of 4 mg/kg intravenously.

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

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Cats:

Common (1 to 10 animals / 100 animals treated):	Injection site pain Digestive tract disorder[1], Diarrhoea[1], Vomiting[1]
Uncommon (1 to 10 animals / 1000 animals treated):	Bloody diarrhoea, Blood in vomit

[1] Most cases were mild and recovered without treatment.

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site pain[1] Digestive tract disorder[2], Diarrhoea[2], Vomiting[2]
Uncommon (1 to 10 animals / 1000 animals treated):	Tarry stool Decreased appetite

[1] Moderate or severe pain at injection site was uncommon.

[2] Most cases were mild and recovered without treatment.

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

Subcutaneous use.

Administer the solution subcutaneously to cats or dogs approximately 30 minutes before the start of surgery, for example around the time of induction of general anaesthesia, at a dose of 1 ml per 10 kg of body weight (2 mg/kg). After surgery in cats, once daily treatment may be continued at the same dosage and at the same time every day for up to 2 days. After soft tissue surgery in dogs, once daily treatment may be continued at the same dosage and at the same time every day for up to 2 days.

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

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 recommended doses for the two formulations may be different.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Store in a refrigerator (2 °C – 8 °C). Avoid introduction of contamination. Keep the vial in the outer carton. Do not use this veterinary medicinal product after the expiry date which is stated on the label or bottle after Exp. The expiry date refers to the last day of that month. After first broaching of the vial, the product may be stored for 28 days. Refrigeration is not required during the 4-week in-use period after first broaching of the vial. Once the vial is broached, using the shelf-life after first opening, calculate the discard date and record in the space provided.

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 52127/5021

Cardboard box containing 1 vial with 20 ml solution for injection.

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

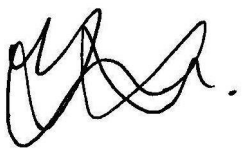
Manufacturer responsible for batch release:

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 cats and dogs, robenacoxib reduced pain, inflammation and fever at the recommended doses with a rapid onset of action (1 h). In clinical trials this product reduced pain and inflammation in cats and dogs undergoing orthopaedic or soft tissue surgery, and reduced the need for rescue treatment in dogs undergoing soft tissue surgery.



Approved: 12 October 2023