

Onsior® Cat Package Leaflet

PACKAGE LEAFLET FOR:

Onsior 6 mg tablets for cats

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 6 mg tablets for cats
Robenacoxib

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

Each tablet contains 6 mg robenacoxib.

Tablets are round, beige to brown, non-divisible and with imprints "NA" on one side and "AK" on the other side.

Onsior tablets are easy to administer and well accepted by most cats.

4. INDICATION(S)

For the treatment of acute pain and inflammation associated with musculo-skeletal disorders 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, lactating or cats used for breeding because the safety of this product has not been established in these animals.

6. ADVERSE REACTIONS*

Mild and transient diarrhoea, soft faeces or vomiting were commonly reported.

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

Cat

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. Administer once daily at the same time every day, for up to 6 days according to the table below.

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

9. ADVICE ON CORRECT ADMINISTRATION

Give either without food or with a small amount of food. Onsior tablets are easy to administer and well accepted by most cats. 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 30°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 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.

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.

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 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 may 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 cats are available in cardboard boxes containing 1, 2, 5 or 10 blisters. Each blister contains 6 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. This product reduced pain and inflammation associated with musculoskeletal disorders in clinical trials in cats.