Onsiior™
(robenacoxib)
6 mg Tabletten for Cats
For Oral Use in Cats Only

Cautions:
Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:
Onsiior (robenacoxib) is a non-narcotic, non-steroidal anti-inflammatory drug (NSAID) of the coxib class. It is available in tablet form. Do not use in cats weighing less than 5.5 lbs, as cats less than 5.5 lbs cannot be accurately dosed. The first dose should be administered at least 30 minutes prior to surgery, at the same time as the peri-anesthetic agents are given. Onsiior tablets may be given with or without a foodstuff. In cats ≥ 5.5 lbs and ≥ 4 months of age, subsequent doses can be given via the oral tablet, or interchanged with subsequent injections for a maximum of 3 total Onsiior tablets over 3 days, not to exceed one dose per day (see Animal Safety and the Onsiior injection package insert).

Note the dose of Onsiior tablets and Onsiior injection are different. If a second and third tablet dose is dispensed to the client to administer at home, doses should be dispensed in the dispensing envelope with the attached Information for Owners Sheet intact. Do not remove information for Cat Owners Sheet. Record when the first dose was administered on the dispensing envelope. Cats weighing ≥ 13.3 lbs may require two blister cards, each dispensed in an individual dispensing envelope.

Contraindications:
Onsiior tablets should not be used in cats that have a hypersensitivity to robenacoxib or known intolerance to NSAIDs.

Warnings:
For intravenous use in cats, Onsiior tablets may be given with or without a foodstuff. In cats ≥ 5.5 lbs and ≥ 4 months of age, subsequent doses can be given via the oral tablet, or interchanged with subsequent injections for a maximum of 3 total Onsiior tablets over 3 days, not to exceed one dose per day (see Animal Safety and the Onsiior injection package insert).

Additional information about adverse drug experience reporting for animals. Contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

Adverse Reactions:
In a placebo-controlled study, a total of 249 male and female cats representing 6 breeds. 6 months to 13 years old, weighing 5.5 – 15 lbs were included in the field safety analysis. The following table shows the number of cats experiencing each observation.:

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Onsiior 6 mg Tabletten for Cats</th>
<th>Placebo (vehicle control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision site bleeding</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Incision site infection</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Inflammation, weight loss</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Decreased activity, lethargy</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Cystitis, hematuria</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Hematocrit, diarrhea</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Hair loss, exfoliation, bruising</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory, cardiac arrest</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Incontonence, weakness, death</td>
<td>0</td>
<td>4</td>
</tr>
</tbody>
</table>

1 Cats may have experienced more than one of the above reaction during the study.

The most commonly reported adverse reactions in surgical site bleeding, infected surgery sites, lethargy, vomiting and inappetence. Changes in the clinical pathology values were not considered clinically significant.

Post Approval Experience (2015)
The following adverse events are reported on voluntarily post approval reporting. Not all adverse events are reported to FDA/AVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The signs reported are listed in decreasing order of reporting frequency.

Anemia, depression/lethargy, vomiting, elevated BUN, elevated creatinine, renal insufficiency failure, diarrhea, weight loss, dehydration.

In some cases, death has been reported. Some of these cases involved patients that developed renal failure/renal insufficiency.

To report suspected adverse drug events and for technical assistance, contact Enova USA Inc. at 1-888-549-5973.

Additional information about adverse drug experience reporting for animals. Contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth.

In an intravenous administration in cats, robenacoxib has an analog of diclofenac.

Clinical Pharmacology:
An inflammation model in cats, robenacoxib had analogic anti-inflammatory and anti-pyretic actions with a following adverse events of gastrointestinal upset (Vmax = 190 mg/kg) is highly bound to plasma proteins (99%), robenacoxib persists longer in the inflammatory exudate of a tissue cage model than in blood. The median robenacoxib elimination half-life in exudate was about 22 hours versus 2.5 hours and 5.0 hours in blood and tissue, respectively.

Metabolism:
Robenacoxib is extensively metabolized by the liver in cats. The systemic exposure of lactam drugs is also marked. At the same time, the elimination time of lactam drugs from plasma is about 20 – 24 hours. Further, robenacoxib is a very potent effective COX-2 inhibitor. The clinical relevance of this data has not been shown. Robenacoxib is an analog of diclofenac.

Absorption:
Oral administration of robenacoxib tablets at 1 mg/kg without food, peak blood concentrations are attained rapidly in a median Tmax of 0.5 h, a mean Cmax of 1159 ng/ml and a mean AUC of 1337 ng-h/ml. Co-administration of robenacoxib tablets with one of the third daily food ration produced no change in median Tmax (0.5 h), mean Cmax (1301 ng/ml) or mean AUC (1383 ng-h/ml). Co-administration of robenacoxib tablets with the entire daily food ration produced no delay in median Tmax (0.5 h), but a lower mean Cmax (981 ng/ml) and a lower mean AUC (1068 ng-h/ml). The systemic mean bioavailability of robenacoxib tablets was 49% without food. The pharmacokinetics of robenacoxib does not differ between male and female cats.

Distribution:
Robenacoxib has a relatively small volume of distribution (mean Vd = 190 mg/kg) and is highly bound to plasma proteins (99%), robenacoxib persists longer in the inflammatory exudate of a tissue cage model than in blood. The median robenacoxib elimination half-life in exudate was about 22 hours versus 2.5 hours and 5.0 hours in blood and tissue, respectively.

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Elimination:
Robenacoxib is rapidly cleared from blood (mean clearance [CL] = 0.44 L/kg) with an elimination mean half-life (t1/2) of 1.1 hours after intravenous administration. After oral administration of tablets, the terminal mean t1/2 from blood was 1.7 hours. Elimination occurs predominantly through the biliary route (fetal and urinary excretion are 60 and 16.5%, respectively).
Onsirol (robenacoxib) 6 mg Tablets for Cats

For Oral Use In Cats Only

Information for Cat Owners — You should read this information before starting your cat on ONSIROL tablets.

What is ONSIROL?
ONSIROL (robenacoxib) is a prescription non-steroidal, non-steroidal anti-inflammatory (NSAID) of the coxib class. ONSIROL (robenacoxib) is for the control of postoperative pain and inflammation associated with orthopedic surgery (deceleration, ovariohysterectomy [spay], or castration surgery [neuter]) in cats greater than or equal to 5.5 pounds (2.5 kg) and up to and including 10 pounds (4.5 kg) of body weight for a maximum of 3 days.

Onsirol tablets should only be given to cats. Do not give Onsirol tablets to other animals, including dogs. Do not give Onsirol tablets to cats at a dose higher than the maximum dose for their weight. Do not give Onsirol tablets for any condition for which it is not known to be safe.

Onsirol should be given as directed. If you are unsure about how to give Onsirol tablets, contact your veterinarian.

What is the next step if your cat is allergic to Onsirol?
If your cat is allergic to Onsirol, your veterinarian may recommend that you take your cat to the hospital for a cat with a similar reaction.

What kind of side effects can occur when your cat takes Onsirol for postoperative pain and inflammation?

Tell your veterinarian about:

- Any side effects your cat has previously experienced from ONSIROL tablets. Allergic reactions may occur in response to ONSIROL tablets.
- Any allergies your cat has to other drugs or food. Your veterinarian may recommend that you take your cat to the hospital for a cat with a similar reaction.
- Any medical problems or allergies that your cat has now or has had in the past.
- All medications that are given to your cat at any time, including ONSIROL tablets.

How often can your cat's medical condition be monitored by your veterinarian?

You should talk to your veterinarian about:

- The surgery procedure performed on your cat.
- The signs that your cat's medical condition is improving or worsening.
- The risks and benefits of using ONSIROL tablets.

How can you give ONSIROL tablets to your cat?

ONSIROL tablets should be given as directed. Consult your veterinarian before giving ONSIROL tablets to your cat. You can give ONSIROL tablets only once every 24 hours. Do not give ONSIROL tablets to your cat if your cat is allergic to ONSIROL tablets.

Look for the following side effects that may indicate that your cat is having a problem:

- Decrease in appetite
- Vomiting
- Change in bowel movements such as diarrhea or constipation
- Change in drinking or urination
- Change in behavior, such as depression or restlessness

If any of the above signs are noticed in your cat, stop administering ONSIROL tablets and call your veterinarian.

Can ONSIROL tablets be given with other medications?
ONSIROL tablets should not be given with other non-steroidal anti-inflammatory drugs (NSAIDs) — i.e., aspirin, meclofenam or corticosteroids (i.e. prednisolone). Always tell your veterinarian about all medications that you give your cat. Consult your veterinarian before giving ONSIROL tablets to your cat.

What can I do if my cat eats more than the prescribed amount of ONSIROL tablets?
Contact your veterinarian immediately if your cat eats more than the prescribed amount of ONSIROL tablets.

What else should I know about ONSIROL tablets?
This sheet provides a summary of information about ONSIROL tablets. If you have any questions or concerns about ONSIROL or postoperative pain and inflammation, talk to your veterinarian.

As with all prescribed medications, ONSIROL tablets should only be given to the cat for which they are prescribed. They should be given to your cat only for the condition for which they were prescribed, at the prescribed dose, as directed by your veterinarian.

NADA #141-320. Approved by FDA
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