CHEWABLE TABLETS

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Dear Caregiver:

Moxicarb, also known as aclacinomycin A, is a semisynthetic, broad-spectrum, enolic form of chloramphenicol derived from the actinomycete Streptomyces clavuligerus. It is used in the treatment of certain bacterial infections, including pneumonia, meningitis, septicemia, and urinary tract infections. Moxicarb is available in a suspension formulation for oral administration in children and adults. It is also available as a fixed-dose combination with amoxicillin and clavulanate potassium, marketed as Augmentin ES.

Moxicarb has a narrow margin of safety and is contraindicated in patients with a history of allergic reactions to any penicillin, cephalosporin, or related compounds. It may also cause serious allergic reactions, including anaphylaxis, in patients with a history of a penicillin allergy.

Moxicarb is a potent beta-lactamase inhibitor and is effective against strains of bacteria that produce beta-lactamase. It is available in a range of concentrations, including 500 mg/125 mg, 500 mg/250 mg, and 875 mg/125 mg. It is usually administered orally twice daily, with or without food, and may be given with or without liquids.

Moxicarb is excreted primarily in the urine and to a lesser extent in the feces. Its plasma half-life is approximately 2 to 3 hours, and its elimination is mainly renal. Approximately 80% of a single oral dose is recovered in the urine, with less than 2% excreted in the feces.

Adverse Reactions:

Moxicarb is generally well tolerated. The most common adverse reactions reported during clinical trials were diarrhea, nausea, vomiting, and abdominal pain. Serious adverse reactions such as anaphylaxis, agranulocytosis, and aplastic anemia have been reported in rare cases.

Moxicarb is available through the Maxisafe program, which provides free samples for new users and discounts for continuing users. Maxisafe is a registered trademark of the manufacturer, Pfizer Inc.

For access in dogs only.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For use in dogs only. This product is not effective in treating gastrointestinal ulceration due to aspirin or other NSAIDs.

Both the N-acetyl-cysteine and the placebo group had similar decreases in Serum creatinine, creatinine clearance, and blood urea nitrogen, and no significant differences were observed between the groups for any of these markers. The differences in these parameters between the groups were not statistically significant. Therefore, these results do not support the use of N-acetyl-cysteine as a prophylactic agent for the prevention of renal injury caused by NSAIDs.

In conclusion, the results of this study suggest that N-acetyl-cysteine may have a limited role in the prevention of renal injury caused by NSAIDs. However, further research is needed to determine the efficacy and safety of this agent in clinical settings.

References:


Pharmacodynamics: The elimination half-life of firocoxib (PREVICOX) is approximately 20% when administered as a single oral dose to adult dogs. Firocoxib is rapidly cleared from the blood and distributed to tissues. The estimated volume of distribution is 13.0 L/kg (5.0 mL/kg). Therefore, a large volume of plasma protein binding (>99%) is saturated. The oral clearance of firocoxib is highly variable among subjects. An assessment of PREVICOX in food-drug abuse interactions study was conducted in normal beagle dogs (12 dogs/group, total of 24 dogs). Firocoxib (13.0 mg/kg) was administered to fasted dogs by oral gavage and to fasted dogs by oral gavage given food immediately after dosing. The results showed that food consumption has no effect on the rate or extent of absorption of firocoxib. Thus, PREVICOX Chewable Tablets can be administered with or without food.

Dosage and Administration: Always provide the Client Information Sheet with precautions. Carefully consider the potential benefits and risks of PREVICOX and other treatments available before deciding to use PREVICOX. Use this brief guide to see if the benefit of the treatment outweighs the possible risk. This product is not for use in human, not for use in horses.

For oral use only. Do not use for the diseases shown in the recommend dose table. See table below. In dogs less than 32 lbs. (14.5 kg), the control group was evaluated for safety. Of the 226 dogs, 118 were given PREVICOX Chewable Tablets at a dose of 2.27 mg/lb (5.0 mg/kg) orally every 24 hours for up to 26 days. The following adverse reactions were observed. Dogs may have experienced more than one of the observed adverse reactions during the study.

**Adverse Reactions Seen in the Soft-tissue Surgery Postoperative Pain Field Studies**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Firocoxib Group (n=108)</th>
<th>Control Group (n=110)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Vomiting</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Decreased Appetite or Anorexia</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Somnolence</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Urinary Incontinence</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

**Adverse Reactions Seen in the Orthopedic Surgery Postoperative Pain Field Studies**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Firocoxib Group (n=118)</th>
<th>Control Group (n=108)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative Pain and Inflammation</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Urinary Incontinence</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Decreased Appetite or Anorexia</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Somnolence</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

For technical assistance or to report suspected adverse events, call 1-888-637-4251. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-800-231-4758, FDA animal drugs. The product label includes the following warning: "Adverse Reactions: The most common adverse reactions reported in clinical studies were gastrointestinal (34%), dermatological (18%), musculoskeletal (12%), and neurological (6%)."