CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number  74-754

FINAL PRINTED LABELING
KETOROLAC TROMETHAMINE TABLETS USP, 10 MG
CONTAINER LABELS, 1000's

NDC 0093-0314-10
KETOROLAC TROMETHAMINE Tablets, USP
10 mg
Each tablet contains:
Ketorolac Tromethamine, USP 10 mg
Caution: Federal law prohibits dispensing without prescription.

Usual Dose: One tablet every 4 to 6 hours. See package insert for full prescribing information.

Keep this and all medications out of the reach of children.

Keep this and all medications out of the reach of children.

NDC 0093-0314-10
KETOROLAC TROMETHAMINE Tablets, USP
10 mg
Each tablet contains:
Ketorolac Tromethamine, USP 10 mg
Caution: Federal law prohibits dispensing without prescription.
**Table 1**

<table>
<thead>
<tr>
<th>Phenomenon</th>
<th>Infant</th>
<th>Neonate 1</th>
<th>Neonate 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenomenon 1</td>
<td>1.0</td>
<td>1.2</td>
<td>1.5</td>
</tr>
<tr>
<td>Phenomenon 2</td>
<td>0.5</td>
<td>0.7</td>
<td>1.0</td>
</tr>
</tbody>
</table>

**Table 2**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
<th>Linear Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable A</td>
<td>Linear relationship</td>
<td>Linear relationship</td>
</tr>
<tr>
<td>Variable B</td>
<td>Linear relationship</td>
<td>Linear relationship</td>
</tr>
</tbody>
</table>

**Table 3**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Linear Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A</td>
<td>Linear relationship</td>
<td>Linear relationship</td>
</tr>
<tr>
<td>Category B</td>
<td>Linear relationship</td>
<td>Linear relationship</td>
</tr>
</tbody>
</table>

**Table 4**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
<th>Linear Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter A</td>
<td>Linear relationship</td>
<td>Linear relationship</td>
</tr>
<tr>
<td>Parameter B</td>
<td>Linear relationship</td>
<td>Linear relationship</td>
</tr>
</tbody>
</table>

**Table 5**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
<th>Linear Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter A</td>
<td>Linear relationship</td>
<td>Linear relationship</td>
</tr>
<tr>
<td>Parameter B</td>
<td>Linear relationship</td>
<td>Linear relationship</td>
</tr>
</tbody>
</table>
Clinical Studies

The antiepileptic efficacy of midazolam was compared with placebo in two double-blind, parallel-group, multicenter studies. Patients with epilepsy (partial and generalized) were randomized to receive midazolam or placebo for 4 weeks before receiving placebo or midazolam for an additional 4 weeks. During the placebo period patients received placebo, and during the midazolam period patients received midazolam 3 mg four times a day. The incidence of seizures was recorded for each patient during the placebo and midazolam periods. A total of 120 patients were enrolled in the studies, 60 in each group. The efficacy of placebo in the two studies was similar.

The results of the studies were as follows:

1. In the study with 109 patients, the mean change in seizure frequency was significantly greater in the midazolam group than in the placebo group. The mean decrease in seizure frequency was 44% in the midazolam group and 12% in the placebo group. The difference was statistically significant (p < 0.05).

2. In the study with 111 patients, the mean change in seizure frequency was significantly greater in the midazolam group than in the placebo group. The mean decrease in seizure frequency was 50% in the midazolam group and 20% in the placebo group. The difference was statistically significant (p < 0.05).

The results of the two studies were consistent, and the efficacy of midazolam was similar in both studies. The incidence of adverse effects was low in both groups, and there were no significant differences between the groups in terms of adverse effects.

The results of these studies suggest that midazolam is effective in reducing the frequency of seizures in patients with epilepsy. However, further studies are needed to confirm these findings and to determine the optimal dosage and duration of treatment.
INDICATIONS IN CHILDREN

Body as a Whole: weight gain, fever, infections, asthma

Dermatologic: lichen planus, petechia

Endocrine: hypothyroidism, diabetes mellitus

Gastrointestinal: anemia, acute gastritis

General: anxiety, depression

Hematologic: neutropenia, purpura, urticaria, purpura fulminans

INCIDENCE IN CHILDREN

Body as a Whole: weight gain, fever, infections, asthma

Dermatologic: lichen planus, petechia

Endocrine: hypothyroidism, diabetes mellitus

Gastrointestinal: anemia, acute gastritis

General: anxiety, depression

Hematologic: neutropenia, purpura, urticaria, purpura fulminans

INCIDENCE IN ADULTS

Body as a Whole: weight gain, fever, infections, asthma

Dermatologic: lichen planus, petechia

Endocrine: hypothyroidism, diabetes mellitus

Gastrointestinal: anemia, acute gastritis

General: anxiety, depression

Hematologic: neutropenia, purpura, urticaria, purpura fulminans

OVERDOSAGE

Initial symptoms include: 200 mg of meprobamate (150 mg/m2/m2/day) for 2 days. Some have reported severe gastrointestinal symptoms such as abdominal pain and diarrhea. Meprobamate is contraindicated in advanced liver failure and patients with known history of liver disease or kidney disease.

CAUTION: Federal law prohibits dispensing without prescription.

Manufactured by Lederle Laboratories

Seybold, PA

Printed in U.S.A.

1985

115821