**INDICATIONS AND USE**

NYMALIZE is a dihydropyridine calcium channel blocker indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (i.e., Hunt and Hess Grades 1-5).

**DOSE AND ADMINISTRATION**

- Administer only enterally (i.e., oral, nasogastric tube, or gastric tube routes). Do not administer intravenously or by other parenteral routes (2.1)
- Give one hour before a meal or two hours after a meal (2.1)
- Start dosing within 96 hours of the onset of SAH (2.1)
- Recommended dose is 20 mL (60 mg) every 4 hours for 21 consecutive days (2.2)
- Nasogastric or Gastric Tube Administration: Administer 20 mL (60 mg) every 4 hours with supplied syringe. Fill remaining contents from nasogastric or gastric tube into stomach (2.3)
- Patients with Cirrhosis: Reduce dose to 10 mL (30 mg) every 4 hours (2.4)

**ADVERSE REACTIONS**

- Hypotension: Monitor blood pressure (4.1)
- Hematologic: Monitor blood counts (4.1)
- CYP3A4 Strong Inducers: May significantly increase risk of hypotension. Concomitant use with NYMALIZE should generally be avoided (5.3)
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Table 3: Degree of Recovery or Disability in Study 3 (89% Hunt and Hess Grades I-III)

<table>
<thead>
<tr>
<th>Study Grade</th>
<th>Treatment</th>
<th>Number of Patients with Any Deficit Due to Spasm</th>
<th>Numbers with Severe Deficit</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-II</td>
<td>Nimodipine 20-30 mg every 4 hours</td>
<td>56</td>
<td>13</td>
</tr>
<tr>
<td>I-II</td>
<td>Placebo</td>
<td>68</td>
<td>11</td>
</tr>
</tbody>
</table>

Study 3 was a 554-patient trial that included SAH patients with all grades of severity (89% were in Hunt and Hess Grades I-III). In Study 3, patients were randomized to nimodipine or placebo. NYMALIZE (nimodipine oral solution) has comparable bioavailability to nimodipine oral capsules.

Table 5: Glasgow Outcome Scale in Combined Studies 3 and 4

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Nimodipine (n=313)</th>
<th>Placebo (n=310)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good Recovery</td>
<td>22 (7.1%)</td>
<td>11 (3.6%)</td>
</tr>
<tr>
<td>Moderate Disability</td>
<td>8 (2.6%)</td>
<td>12 (3.9%)</td>
</tr>
<tr>
<td>Severe Disability</td>
<td>6 (1.9%)</td>
<td>15 (4.9%)</td>
</tr>
<tr>
<td>Vegetative Survival</td>
<td>4 (1.3%)</td>
<td>6 (1.9%)</td>
</tr>
<tr>
<td>Death</td>
<td>47 (15.1%)</td>
<td>54 (17.5%)</td>
</tr>
</tbody>
</table>

*p = 0.045, nimodipine vs. placebo

A dose-ranging study comparing 30 mg, 60 mg, and 90 mg doses found a generally low rate of spasm-related neurological deficits but no dose response relationship.

16 HOW SUPPLIED/STORAGE AND HANDLING

- NDC 24338-200-16: 16 oz. bottle (473 mL)
- NDC 24338-200-12: Carton containing 12 individually wrapped packages. Each package contains one 20 mL Unit-Dose cup (NDC 24338-200-20) and one oral syringe.

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Protect from light. Do not refrigerate.