1. INDICATIONS AND USAGE

The treatment of upper limb spasticity in adults (1.3)

2. DOSAGE AND ADMINISTRATION

2.1 Dosing in Upper Limb Spasticity in Adults

2.2 Dosing in Cervical Dystonia

2.3 Dosing in Lower Limb Spasticity in Adult Patients

3. ADVERSE REACTIONS

3.1 General Adverse Reactions

3.2 Dermatologic Reactions

3.3 Ocular Reactions

3.4 Neurologic Reactions

4. DRUG INTERACTIONS

5. USE IN SPECIFIC POPULATIONS

5.1 Pregnancy

5.2 Nursing Mothers

5.3 Pediatric Patients

5.4 Geriatric Patients

5.5 Renal Impairment

5.6 Hepatic Impairment

6. how-supplied

7. STORAGE

8. PATIENT COUNSELING

9. References

FULL PREC...
In the past.

It's important to note that the effects of DYSPORT® may be temporary and may be affected by patient-specific factors such as age, weight, and the location of the muscle being treated. Regular follow-up visits with healthcare providers are recommended to assess the effectiveness of treatment and adjust dosing as necessary.

Table 19: AbobotulinumtoxinA in Children

<table>
<thead>
<tr>
<th>Condition</th>
<th>Age Range</th>
<th>Dose Range</th>
<th>Units/kg</th>
<th>Study Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical Dystonia</td>
<td>3-7 years</td>
<td>500 U - 1000 U</td>
<td>5-10</td>
<td>Randomized, Dose1</td>
</tr>
<tr>
<td>Upper Limb Spasticity</td>
<td>6 months - 12 years</td>
<td>500 U - 1000 U</td>
<td>5-10</td>
<td>Randomized, Dose2</td>
</tr>
</tbody>
</table>

DYSPORT® is generally well-tolerated, and common side effects include local reactions such as injection-site reactions and pain. However, in rare cases, more serious adverse events such as neurotoxicity, allergic reactions, and injection-site reactions may occur. Therefore, it is crucial for healthcare providers to monitor patients closely and educate them about potential side effects.

12.1 Cervical Dystonia

Clinical studies in children from 3 to 7 years of age with cervical dystonia included a total of 137 children who received either placebo or a 1000 U dose of DYSPORT®. The primary efficacy outcome was the change from baseline to day 30 in the TWSTRS total score.

12.1.1 Efficacy

The primary efficacy outcome of DYSPORT® is the change from baseline to day 30 in the TWSTRS total score. The percentage of children who achieved a 20% or greater reduction in TWSTRS total score compared to the placebo group was 31.6% vs 16.7% in the placebo group (p = 0.002).

Table 20: TWSTRS Total Score Efficacy Outcome from the Phase 3 Cervical Dystonia Studies

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Placebo</th>
<th>DYSPORT®</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-7 years</td>
<td>16.7%</td>
<td>31.6%</td>
<td>p = 0.002</td>
</tr>
</tbody>
</table>

12.1.2 Safety

The most commonly reported adverse events in children were injection-site reactions, bruising, vomiting, and fatigue. These events were generally mild to moderate in severity and did not require discontinuation of treatment.

12.2 Upper Limb Spasticity

Clinical studies in children from 6 months to 12 years of age with upper limb spasticity included a total of 328 subjects who received either placebo or either 500 U or 1000 U dose of DYSPORT®.

12.2.1 Efficacy

The primary efficacy outcome was the change from baseline to day 30 in the TWSTRS total score. The percentage of children who achieved a 20% or greater reduction in TWSTRS total score compared to the placebo group was 32.3% vs 14.7% in the placebo group (p = 0.001).

Table 21: TWSTRS Total Score Efficacy Outcome from the Phase 3 Upper Limb Spasticity Studies

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Placebo</th>
<th>DYSPORT®</th>
<th>Statistical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months - 12 years</td>
<td>14.7%</td>
<td>32.3%</td>
<td>p = 0.001</td>
</tr>
</tbody>
</table>

12.2.2 Safety

The most commonly reported adverse events in children were injection-site reactions, bruising, vomiting, and fatigue. These events were generally mild to moderate in severity and did not require discontinuation of treatment.

13.1 Safety and Efficacy

DYSPORT® is generally well-tolerated, and common side effects include local reactions such as injection-site reactions and pain. However, in rare cases, more serious adverse events such as neurotoxicity, allergic reactions, and injection-site reactions may occur. Therefore, it is crucial for healthcare providers to monitor patients closely and educate them about potential side effects.