What is the most important information I should know about DYSPORT®?

DYSPORT® may cause serious side effects that can be life threatening including:

- Problems breathing or swallowing
- Spread of toxin effects
- These problems may happen within hours, or days to weeks after an injection of DYSPORT®
- If you have any of these problems after treatment with DYSPORT®, call your doctor right away.

1. Problems swallowing, speaking, or breathing. These problems can happen within hours, or days to weeks after an injection of DYSPORT® usually because the muscles that help you to breathe and swallow can weaken after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with DYSPORT®.

- People who have certain breathing problems may need to use machines in their home to help them breathe. These patients may need to be monitored.
- Swallowing problems may last for several weeks. People who cannot swallow well may need a feeding tube to help them eat and drink. If swallowing problems are severe, food or fluids may go down your lungs. People who have swallowing problems should not eat or drink anything by mouth until you talk to your doctor.

2. Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas or muscles away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:
- Loss of strength and muscle weakness all over your body
- Blurred vision and drooping eyelids
- Trouble speaking or words come out slurred
- Double vision
- Loss of balance or change in bowel or bladder function
- Trouble swallowing

These symptoms may happen within hours, or days to weeks after you receive an injection of DYSPORT®. These problems may make it unsafe for you to drive a car or do other dangerous activities. See “What should I avoid while receiving DYSPORT®?”

What is DYSPORT®?

DYSPORT® is a prescription medicine that is injected into muscles and used:
- To treat cervical dystonia (CD) in adults
- To treat the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 60 years of age for a short period of time (temporarily)
- To treat increased muscle stiffness in adults with upper limb spasticity
- To treat increased muscle stiffness in children 2 years of age and older with cerebral palsy whom have lower limb spasticity and for whom spinal botox has been shown to be effective
- To treat increased muscle stiffness in children 2 years of age and older with lower limb spasticity and for whom spinal botox has been shown to be effective
- To treat upper limb spasticity
- To treat lower limb spasticity
- To treat muscles of the lower limb(s) when possible, the dose should be distributed across more than one injection site
- For the treatment of cervical dystonia, glabellar lines, and upper limb spasticity in adults
- For the treatment of lower limb spasticity in adults
- For the treatment of upper limb spasticity in children 12 years of age and older

Who should not take DYSPORT®?

Do not take DYSPORT® if you:
- Are allergic to DYSPORT® or any of the ingredients in DYSPORT®. See the end of this Medication Guide for a list of ingredients in DYSPORT®
- Have had an anaphylactic (allergic) reaction to any other botulinum toxin product such as Myobloc® (rimabotulinumtoxinA), Botox® (onabotulinumtoxinA), or Xeomin® (incobotulinumtoxinA)

What should I tell my doctor before taking DYSPORT®?

Tell your doctor about all your medical conditions, including:
- If you have a disease that affects your muscles (such as myasthenia gravis or Lambert-Eaton syndrome). See “What is the most important information I should know about DYSPORT®?”
- If you have allergies to any botulinum toxin product
- If you have had breathing problems
- If you have had swallowing problems
- If you have had bleeding problems
- If you have diabetes
- If you have had a slow heart beat or other problem with your heart rate or rhythm
- If you plan to have surgery
- If you have peptic ulcer disease
- If you have had an anaphylactic (allergic) reaction to any other botulinum toxin product in the past
- If you plan to become pregnant
- If you are pregnant or plan to become pregnant. It is not known if DYSPORT® can harm your unborn baby

...
Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal products. Using DYSPORT® with certain other medicines may cause serious side effects. Do not start any new medicines until you have told your doctor that you have received DYSPORT® in the past.

Tell your doctor if you:
- have received any other botulinum toxin product in the last four months
- have received injections of botulinum toxin such as Myobloc® (rimabotulinumtoxinB), Botox® (onabotulinumtoxinA), or Xeomin® (incobotulinumtoxinA) in the past, be sure your doctor knows exactly which product you received
- have recently received an antibiotic by injection
- take muscle relaxants
- take an allergy or cold medicine
- take a sleeping medicine

Ask your doctor if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take DYSPORT®?
- DYSPORT® is an injection that your doctor will give you
- DYSPORT® is injected into the affected muscles
- If you are an adult, your doctor may give you another dose of DYSPORT® after 12 weeks or longer, if it is needed
- If you are an adult being treated for CD or upper limb spasticity or you are a child (2 to 17 years of age) being treated for lower limb spasticity, your doctor may change your dose of DYSPORT®, until you and your doctor find the best dose for you. Children should not be re-treated sooner than every 12 weeks.
- The dose of DYSPORT® is not the same as the dose of any other botulinum toxin product

What should I avoid while taking DYSPORT®?
- DYSPORT® may cause loss of strength or general muscle weakness, blurred vision, or drooping eyelids within hours to weeks of taking DYSPORT®. If this happens, do not drive a car, operate machinery, or do other dangerous activities. See "What is the most important information I should know about DYSPORT®?"
- What are the possible side effects of DYSPORT®? DYSPORT® can cause serious side effects. See "What is the most important information I should know about DYSPORT®?"

The most common side effects of DYSPORT® are people with cervical dystonia include:
- muscle weakness
- dry mouth
- feeling of tiredness
- muscle pain
- problems speaking
- eye problems
- difficulty swallowing
- headache

The most common side effects of DYSPORT® are people with glabellar lines include:
- stuffy or runny nose and sore throat
- injection site pain
- upper respiratory infection
- blood in urine
- headache
- injection site reaction
- swelling of eyelids
- drooping eyelids
- sinus infection
- rash

The most common side effects of DYSPORT® are people with lower limb spasticity include:
- urinary tract infection
- muscle weakness
- exacerbation of pain
- fall
- depression
- stuffy or runny nose and sore throat
- dizziness

The most common side effects of DYSPORT® in children (2 to 17 years of age) with lower limb spasticity include:
- upper respiratory infection
- stuffy or runny nose and sore throat
- flu
- cough
- sneeze

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of DYSPORT®. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about DYSPORT®:
- Medications are sometimes prescribed for purposes other than those listed in a Medicated Guide. This Medicated Guide summarizes the most important information about DYSPORT®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DYSPORT® that is written for healthcare professionals.
- What are the ingredients in DYSPORT®?
- Active ingredient: Botulinum toxin Type A
- Inactive ingredients: Human albumin and lactose. DYSPORT® may contain casein’s milk protein.
- For more information about DYSPORT®, call 877-397-7871 or go to www.dy sportstx.com.

This Medicated Guide has been approved by the U.S. Food and Drug Administration.

Table 13: Administration of DYSPORT® for Upper Limb Spasticity in Adults

<table>
<thead>
<tr>
<th>Site</th>
<th>Placebo n=50</th>
<th>DYSPORT® n=398 (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td>0</td>
<td>2 (0.5)</td>
</tr>
<tr>
<td>Shoulder</td>
<td>0</td>
<td>4 (1.0)</td>
</tr>
<tr>
<td>Arm</td>
<td>2</td>
<td>10 (2.5)</td>
</tr>
<tr>
<td>Hand</td>
<td>0</td>
<td>2 (0.5)</td>
</tr>
</tbody>
</table>

*Categorizes the number of subjects who received any injections in a particular area. n=398 (%)*

Table 14: Administration of DYSPORT® for Lower Limb Spasticity in Pediatric Patients

<table>
<thead>
<tr>
<th>Site</th>
<th>Placebo n=79</th>
<th>DYSPORT® n=157 (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee</td>
<td>0</td>
<td>1 (0.6)</td>
</tr>
<tr>
<td>Leg</td>
<td>0</td>
<td>3 (1.9)</td>
</tr>
</tbody>
</table>

*Categorizes the number of subjects who received any injections in a particular area. n=157 (%)*

Table 15: DYSPORT® Dose Injected and Number of Injections per Muscle in Adult Upper Limb Spasticity Study

<table>
<thead>
<tr>
<th>Muscle</th>
<th>Placebo n=43</th>
<th>DYSPORT® n=163 (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexor digitorum superficialis</td>
<td>0</td>
<td>3 (1.8)</td>
</tr>
<tr>
<td>Flexor digitorum profundus</td>
<td>0</td>
<td>5 (3.1)</td>
</tr>
<tr>
<td>Flexor carpi ulnaris</td>
<td>0</td>
<td>4 (2.5)</td>
</tr>
</tbody>
</table>

*Categorizes the number of subjects who received any injections in a particular muscle. n=163 (%)*

Table 16: Adverse Reactions in CD or Upper Limb Spasticity Study

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Placebo n=50</th>
<th>DYSPORT® n=398 (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>5</td>
<td>31 (7.8)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2</td>
<td>7 (1.8)</td>
</tr>
<tr>
<td>Nausea</td>
<td>1</td>
<td>2 (0.5)</td>
</tr>
</tbody>
</table>

*Categorizes the number of subjects who received any injections in a particular area. n=398 (%)*