MEDICATION GUIDE
DYSPORT® (*DIS-port*)
(abobotulinumtoxinA)
for Injection

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 can happen within hours, or days to weeks after an injection of DYSPORT®. Call your doctor or get medical help right away if you have any of these problems after treatment with DYSPORT®:

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 you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with DYSPORT®.

- People with certain breathing problems may need to use muscles in their neck to help them breathe. These patients may be at greater risk for serious breathing problems with DYSPORT®.
- Swallowing problems may last for several weeks. People who cannot swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving DYSPORT® have the highest risk of getting these problems.

2. Spread of toxin effects. In some cases, the effect of botulinum toxin may affect areas of the body 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 the body
- blurred vision and drooping eyelids
- trouble saying words clearly (dysarthria)
- trouble breathing
- double vision
- hoarseness or change or loss of voice (dysphonia)
- loss of bladder control
- trouble swallowing

These symptoms can happen within hours, or days to weeks after you receive an injection of DYSPORT®. These problems could 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 improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary)
- to treat increased muscle stiffness in, elbow, wrist, and finger muscles in adults with upper limb spasticity
- to treat increased muscle stiffness in calf muscles in children 2 years of age and older with lower limb spasticity.

CD is caused by muscle spasms in the neck. These spasms cause abnormal position of the head and often neck pain. After DYSPORT® is injected into muscles; those muscles are weakened for up to 12 to 16 weeks or longer. This may help lessen your symptoms.

Frown lines (wrinkles) happen because the muscles that control facial expression are used often (muscle tightening over and over). After DYSPORT® is injected into the muscles that control facial expression, the medicine stops the tightening of these muscles for up to 4 months.

Upper limb spasticity is caused by muscle spasms in the elbow, wrist, and finger muscles. These spasms cause an abnormal position of these muscles. After DYSPORT® is injected into muscles, those muscles are weakened for up to 12 to 16 weeks or longer. This may help lessen your symptoms.

Lower limb spasticity is caused by muscle spasms in calf muscles. These spasms cause an abnormal position of these muscles. After DYSPORT® is injected into muscles, those muscles are weakened for up to 16 to 22 weeks or longer. This may help lessen your symptoms.

- For the treatment of cervical dystonia, glabellar lines, and upper limb spasticity in adults, it is not known whether DYSPORT® is safe or effective in children under 18 years of age.
- For the treatment of lower limb spasticity, it is not known whether DYSPORT® is safe or effective in children under 2 years of age.
- It is not known whether DYSPORT® is safe or effective for the treatment of other types of muscle spasms.
- It is not known whether DYSPORT® is safe or effective for the treatment of other wrinkles.

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®

- are allergic to cow's milk protein
- had an allergic reaction to any other botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Botox® (onabotulinumtoxinA), or Xeomin® (incobotulinumtoxinA).
- have a skin infection at the planned injection site

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 and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome). See "What is the most important information I should know about DYSPORT®?"
- have allergies to any botulinum toxin product
- had any side effect from any botulinum toxin product in the past
- have or have had a breathing problem, such as asthma or emphysema
- have or have had swallowing problems
- have or have had bleeding problems
- have diabetes
- have or have had a slow heart beat or other problem with your heart rate or rhythm
- have plans to have surgery
- had surgery on your face
- have weakness of your forehead muscles (such as trouble raising your eyebrows)
- have drooping eyelids
- have any other change in the way your face normally looks
- are pregnant or plan to become pregnant. It is not known if DYSPORT® can harm your unborn baby
- are breast-feeding or planning to breast-feed. It is not known if DYSPORT® passes into breast milk

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.**

Especially 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 sleep 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 retreated 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® in people with cervical dystonia include:

- muscle weakness
- muscle pain
- difficulty swallowing
- dry mouth
- problems speaking
- feeling of tiredness
- eye problems
- headache

The most common side effects of DYSPORT® in people with glabellar lines include:

- stuffy or runny nose and sore throat
- headache
- drooping eyelids

- injection site pain
- injection site reaction
- sinus infection
- upper respiratory infection
- swelling of eyelids
- nausea
- blood in urine

The most common side effects of DYSPORT® in adults with upper limb spasticity include:

- urinary tract infection
- fall
- stuffy or runny nose and sore throat
- muscle weakness
- depression
- dizziness
- musculoskeletal pain

The most common side effects of DYSPORT® in children (2 to 17 years of age) with lower limb spasticity include:

- upper respiratory infection
- flu
- fever
- stuffy or runny nose and sore throat
- cough

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®:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
This Medication 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 cow's milk protein.

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For more information about DYSPORT®, call 877-397-7671 or go to www.dysport.com or www.DysportUSA.com.
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