

## **IMPORTANT SAFETY INFORMATION for Dysport**

### **What is the most important information you should know about Dysport?**

**Spread of Toxin Effects:** In some cases, the effects of Dysport and all botulinum toxin products may affect areas of the body away from the injection site. These effects can cause symptoms of a serious condition called botulism. Symptoms of botulism can happen hours to weeks after injection and may include swallowing and breathing problems, loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, or loss of bladder control. Swallowing and breathing problems can be life threatening and there have been reports of death.

The risk of symptoms is probably greatest in children and adults treated for muscle spasms, particularly in those patients who have underlying medical conditions that could make these symptoms more likely.

The toxic effects have been reported at doses similar to those used to treat muscle spasms in the neck. Lower doses, in both approved and unapproved uses, have also caused toxic effects. This includes treatment of children and adults for muscle spasms.

These effects could make it unsafe for you to drive a car, operate machinery, or do other dangerous activities.

**Do not have Dysport treatment if you:** are allergic to Dysport or any of its ingredients (see the end of the Medication Guide for a list of ingredients), are allergic to cow's milk protein, had an allergic reaction to any other botulinum toxin product, such as Myobloc® or Botox®, or have a skin infection at the planned injection site.

The dose of Dysport is not the same as the dose of any other botulinum toxin product. The dose of Dysport cannot be compared to the dose of any other botulinum toxin product you may have used.

**Dysport may not be right for you if:** you have surgical changes to your face, very weak muscles in the treatment area, your face looks very different from side to side, the injection site is inflamed, you have droopy eyelids or sagging eyelid folds, deep facial scars, thick oily skin, or if your wrinkles can't be smoothed by spreading them apart.

**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), allergies to any botulinum toxin product or had any side effect from any botulinum toxin product in the past, a breathing problem (such as asthma or emphysema), swallowing problems, bleeding problems, diabetes, or a slow heart beat or other problem with your heart rate or rhythm, plans to have surgery, had surgery on your face, weakness of your forehead muscles (such as trouble raising your eyebrows), drooping eyelids, or any other change in the way your face normally looks. Patients with a disease that affects muscles and nerves who are treated with typical doses of Dysport may have a higher risk of serious side effects, including severe swallowing and breathing problems.

### **Human Albumin**

This product contains albumin taken from human plasma. Steps taken during donor screening and product manufacturing processes make the risk of spreading viral diseases extremely rare. In theory, there is also an extremely rare risk of contracting Creutzfeldt-Jakob disease (CJD). No cases of spread of viral diseases or CJD have ever been reported for albumin.

### **Allergic Reaction to Injecting in the Skin**

It is not known if an allergic reaction can be caused by injecting Dysport into the skin. The safety of treating excessive sweating with Dysport is not known.

## **Common Side Effects**

The most common side effects are nose and throat irritation, headache, injection site pain, injection site skin reaction, upper respiratory tract infection, eyelid swelling, eyelid drooping, sinus inflammation, and nausea.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal and other natural products. Using Dysport with certain other medicines may cause serious side effects. Do not start any new medicines while taking Dysport without talking to your doctor first.

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) or Botox® (onabotulinumtoxinA) 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, or take a sleep medicine.

## **Use In Specific Populations**

Dysport should not be used in children or in women who are pregnant or breastfeeding.