Injection Treatment Information – *Anna-Laurie*

Name: *Anna-Laure*
Age: 45

Treatment Information:

- 50 units *Dysport*® (abobotulinumtoxinA) for injection in Glabella
- 4 mL *Restylane-L*® in Nasolabial folds, Upper lip and Lower lips

Time Between Treatment:

- Information unknown

Actual patient. Individual results may vary. Images have not been retouched.

Indication
Dysport is a prescription injection for temporary improvement in the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults less than 65 years of age.

Important Safety Information

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 treated for muscle spasms but symptoms can also occur in adults treated for muscle spasms and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

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.

Ask your doctor if *Dysport* is right for you.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see *Dysport* Full Prescribing Information including Medication Guide.

Indication
Restylane-L® is indicated for mid-to-deep dermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and for lip enhancement in patients over the age of 21.

Important Safety Information

Restylane-L contains traces of gram-positive bacterial protein and is contraindicated for patients with allergies to such material or for patients with severe allergies that have required in-hospital treatment. *Restylane-L* should not be used by patients with bleeding disorders, with hypersensitivity to amide-type local anesthetics, such as lidocaine, or by women who are pregnant or breastfeeding. *Restylane-L* should not be injected anywhere except the dermis or lip submucosa.

Use of *Restylane-L* at the site of skin sores, pimples, rashes, hives, cysts, or infection should be postponed until healing is complete. The most commonly observed side effects are swelling, redness, pain, bruising, and tenderness at the injection site. These are typically mild in severity and resolve in less than 7 days in nasolabial folds and less than 14 days in lips. The incidence of swelling may be higher in patients under 36 years, and the incidence of bruising may be higher in patients over 35 years. Serious but rare side effects include delayed onset infections, recurrence of herpetic eruptions, and superficial necrosis and scarring at the injection site. Do not implant into blood vessels. Use with caution in patients recently treated with anticoagulant or platelet inhibitors to avoid bleeding and bruising.

Treatment volume should be limited to 6.0 mL in wrinkles and folds, such as nasolabial folds, and limited to 1.5 mL per lip, as higher volume significantly increases moderate and severe injection site reactions. The safety or effectiveness of treatment in areas other than nasolabial folds and lips has not been established in controlled clinical studies.

Restylane-L is available only through a licensed practitioner. Complete Instructions for Use are
available at www.RestylaneUSA.com.

GALDERMA

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