

# Dysport<sup>\*</sup>

## (abobotulinumtoxinA)

**Dysport<sup>®</sup> (abobotulinumtoxinA)** 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.<sup>1</sup>

\*Please see full Important Safety Information, including Distant Spread of Toxin Effect Boxed Warning, on page 2



### QUICK FACTS

- » **Natural-Looking:** *Dysport* users maintain their natural facial expressions without the frozen look
- » **Long-Lasting:** Results may last up to 5 months<sup>2-4#</sup>
- » **Fast-Acting:** The majority of users saw improvement in just 2-3 days after treatment<sup>3-5\*\*</sup>
- » **Trusted Results:** *Dysport* has been on the market for 12 years in the U.S. with a proven safety record<sup>1</sup>

\*A secondary endpoint based on Kaplan-Meier estimates of cumulative rate of time to onset of response. The median time to onset of response was 3 days in GL-1 (*Dysport* 55/105 [52%], Placebo 3/53 [6%]) and GL-2 (*Dysport* 36/71 [51%], Placebo 9/71 [13%]), and 2 days in GL-3 (*Dysport* 110/200 [55%], Placebo 4/100 [4%]).

#Users = clinical trial subjects

#GL-1 and GL-3 evaluated subjects for at least 150 days following treatment. Based on a ≥1-Grade GLSS improvement from baseline utilizing data from two double-blinded, ran domized, placebo-controlled pivotal studies (GL-1, GL-3) in a post-hoc analysis.

\*\*Subject's satisfaction and self-perception reported 3 weeks after treatment (n=531).

#Design: Multicenter, prospective, non-interventional observational study conducted in France, Germany, Spain and the United Kingdom (n=533). Subjects were eligible if the investigator had decided to prescribe *Dysport* according to the labeling. Subjects completed questionnaires at 3 weeks and 4 months after treatment.

#Results based on subject questionnaire (FACE-Q Age Appraisal VAS), mITT population, 1.5 mL and 2.5 mL reconstitution, N=60.2

#Subject's satisfaction and self perception reported 3 weeks after treatment (n=531).

## WHAT IS *DYS*SPORT FOR INJECTION?

*Dysport* softens and smooths frown lines by blocking the signal from the nerve to the muscles, temporarily helping to prevent contraction of the muscles that cause frown lines.<sup>1</sup> *Dysport* is a neuromodulator, an injection of a small amount of botulinum toxin that treats the frown lines when injected into the underlying muscle, causing it to relax and gradually smooth out the appearance of the frown lines between the eyebrows.<sup>7</sup>

*Dysport* is a quick (10-20 minute) procedure administered by a healthcare specialist. A very small needle is used, with no anesthetic needed, and little to no downtime.

## *DYS*SPORT DELIVERS

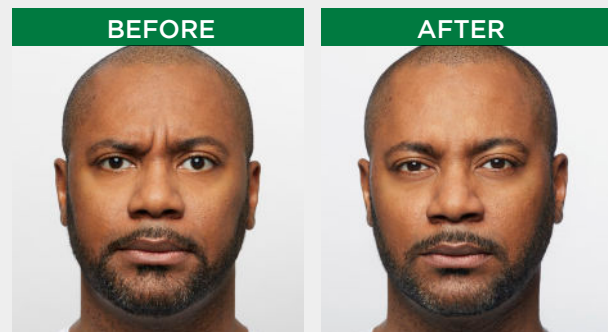
*Dysport* has a proven safety record. It has been on the U.S. market for aesthetic use for 12 years<sup>1</sup> and is approved in 74 countries<sup>8</sup> and has over 27 years of therapeutic and aesthetic clinical experience worldwide.<sup>9</sup> Aesthetic professionals know that they can trust *Dysport* to deliver natural-looking, fast-acting<sup>3-5</sup> and long-lasting<sup>2-4</sup> results. 30 days after treatment with *Dysport*, 92% of users<sup>+</sup> felt confident and attractive.<sup>10</sup> Even four months after *Dysport* treatment, users reported looking about four years younger than they did before treatment.<sup>1,5,10,≡</sup> In fact, 97% of users who received *Dysport* reported that they would receive the treatment again.<sup>11,†,‡</sup>



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



**Frown after 50 units  
Day 10**  
(Individual results may vary)



**Frown after 50 units  
Day 14**  
(Individual results may vary)

For more information, visit [www.dysportusa.com](http://www.dysportusa.com).

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## 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. Symptoms 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. You are at the highest risk if these problems are pre-existing before injection.

**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®, Botox®, or Xeomin®, have a skin infection at the planned injection site, under 18 years of age, or are pregnant or breastfeeding.

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

**Tell your doctor about any swallowing or breathing difficulties and all your muscle or nerve conditions** such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis, or Lambert-Eaton syndrome, which may increase the risk of serious side effects including difficulty swallowing and difficulty breathing. Serious allergic reactions have occurred with the use of *Dysport*. Dry eye has also been reported.

**Tell your doctor about all of your medical conditions, including** if you have surgical changes to your face, very weak muscles in the treatment area, any abnormal facial change, injection site inflammation, droopy eyelids or sagging eyelid folds, deep facial scars, thick oily skin, wrinkles that can't be smoothed by spreading them apart, or if you are pregnant or breastfeeding or planning to become pregnant or breastfeed.

**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, such as Myobloc® (rimabotulinumtoxinB), Botox® (onabotulinumtoxinA), or Xeomin® (incobotulinumtoxinA), in the last four months or any 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.

### 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.

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](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see *Dysport* Full Prescribing Information including Medication Guide at [DysportUSA.com](http://DysportUSA.com)**

<sup>1</sup> *Dysport* for Prescribing Information Insert. Fort Worth, TX: Galderma Laboratories, L.P.; 2020.

<sup>2</sup> Data on file. MA-35497. Post Hoc Analysis. Fort Worth, TX: Galderma Laboratories, L.P., 2017.

<sup>3</sup> Data on file. MA-Y-97-52120-719 (GL-1) Clinical Study Report. Fort Worth, TX: Galderma Laboratories, L.P., 2007.

<sup>4</sup> Data on file. MA-Y-97-52120-718 (GL-3) Clinical Study Report. Fort Worth, TX: Galderma Laboratories, L.P., 2007.

<sup>5</sup> Data on file. MA-Y-97-52120-085 (GL-2) Clinical Study Report. Fort Worth, TX: Galderma Laboratories, L.P., 2007.

<sup>6</sup> Heckmann M, Teichmann B, Schroder U, et al. Pharmacologic denervation of frown muscles enhances baseline expression of happiness and decreases baseline expression of anger, sadness, and fear. *J Cosmet Dermatol.* 2003;49(2):213-216.

<sup>7</sup> NEUROMODULATORS FOR AGING SKIN. American Society for Dermatologic Surgery. 2019. Accessed February 20, 2019. <https://www.asds.net/skin-experts/skin-treatments/neuromodulators/neuromodulators-for-aging-skin>

<sup>8</sup> Data on file. Ipsen World-Wide Marketing Authorisation Status. Fort Worth, TX: Galderma Laboratories, L.P., February 2017.

<sup>9</sup> Medicines and Healthcare products Regulatory Agency (MHRA). Botulinum Toxin Type A Powder For Solution For Injection (Clostridium botulinum toxin type A - Haemagglutinin complex). <http://www.mhra.gov.uk/home/groups/par/documents/websitereferences/con108644.pdf>. Accessed May 11, 2015.

<sup>10</sup> Data on file. GLI.04.SRE.US10348 Clinical Study Report. Fort Worth, TX: Galderma Laboratories, L.P., 2017.

<sup>11</sup> Data on file. 43USD1802 Clinical Study Report. Fort Worth, TX: Galderma Laboratories, L.P., 2020.