# GALDERMA Aesthetic Injectable Products

## Dysport.\* (abobotulinumtoxinA)

# **SCULPTRA®**



Dysport® (abobotulinumtoxinA) for Injection is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults <65 years of age. Dysport should be injected in a 5-point injection pattern with 10 Units/ injection for a total



















(injectable poly-L-lactic acid (PLLA-SCA)) is indicated for use in people with healthy immune systems for the correction of shallow to deep nasolabial fold contour deficiencies, fine lines and wrinkles in the cheek region and other facial wrinkles.

1 to 2 vials/session, with each successive session at least 3 weeks apart. Up to 4 sessions may be needed to achieve full correction.



Restylane® Lyft with Lidocaine is indicated for implantation into the deep dermis to superficial subcutis for the correction of moderate to severe facial folds and wrinkles, such as nasolabial folds, for subcutaneous to supraperiosteal implantation for cheek augmentation, and for the correction of age-related midface contour deficiencies in patients over the age of 21.

One 25G or one 27G 1.5" or 2" DermaSculpt, Softfil, or TSK cannula. Approved for use in the midface only.



Restylane® Eyelight is indicated for the improvement of infraorbital hollowing in patients over the age of 21.

One TSK 25G or one TSK 27G 1.5" or 2" cannula.



Restylane® and Restylane-L® are for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

Restylane and Restylane-L are also indicated for injection into the lips in patients over the age of 21.



Restylane® Silk is for lip augmentation and for correction of perioral wrinkles in patients over the age of 21.

One 25G or one 27G 1.5" DermaSculpt or Softfil cannula. Approved for use in lips only.



Restylane® Defyne is indicated for injection into the mid-to-deep dermis for the correction of moderate to severe deep facial wrinkles and folds, such as nasolabial folds, in patients

over the age of 21. Restylane Defyne is also indicated for injection into the mid-to-deep dermis (subcutaneous and/or supraperiosteal) for

augmentation of the chin

region to improve the chin

profile in patients over the

chin retrusion.

age of 21 with mild to moderate



Restylane® Contour is for cheek augmentation and for the correction of midface contour deficiencies in patients over the age of 21.

One TSK 25G or one TSK 27G 1.5" or 2" cannula. Approved for use in the midface only.



Restylane® Kysse is for lip augmentation and for correction of upper perioral wrinkles in patients over the age of 21.



Restylane® Refyne is for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in patients over the age of 21.

### **INJECTION AREAS**



the brows

of 50 Units.



Cheek wrinkles, nasolabial folds, marionette lines, mental crease (chin wrinkles), preauricular and submalar wrinkles, and pyriform fossa



Nasolabial folds, oral commissures, marionette lines cheeks/midface† contour deficiency, and subcutaneous plane in the dorsal hand

†Can use cannula (midface only).



Infraorbital hollows‡ ‡Can use cannula



Nasolabial folds, lips, oral commissures, marionette lines



Lips§ and perioral rhytids §Can use cannula (lips only).



Nasolabial folds, oral commissures, marionette lines, and chin augmentation



Cheeks/midface|| contour deficiency

||Can use cannula

Moderate flexibility

Very high volume

High lift



Lips and upper perioral rhytids



Nasolabial folds, oral commissures, marionette lines

#### NASHA®

- High firmness
- High volume
- Very high lift
- Lower flexibility Firm
- Lower flexibility • Firm
- Lower flexibility · Moderately firm
- Moderate flexibility
- · High volume
- High lift



## **XpresHAn**

- Moderate flexibility
  - Low volume
  - Low/moderate lift



Highest flexibility



## \*Please see full Important Safety Information for Dysport, including Distant Spread of Toxin Effect Boxed Warning, on the back cover.

Dysport® (abobotulinumtoxinA) for Injection is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adults <65 years of age.

Important Safety Information Distant Spread of Toxin Effect

Postmarketing reports indicate that the effects of *Dysport* and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

#### CONTRAINDICATIONS

- Hypersensitivity to any botulinum toxin product or excipients
- Allergy to cow's milk protein
- Infection at the proposed injection site(s)

#### WARNINGS AND PRECAUTIONS

- The potency Units of Dysport are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of Dysport cannot be compared to or converted into units of any other botulinum toxin products.
- Immediate medical attention may be required in cases of respiratory, speech or swallowing difficulties, or serious hypersensitivity reactions.
- Recommended dose and frequency of administration should not be exceeded.
- Dry eye may occur with glabellar line treatment: if symptoms persist, consider referring patient to an ophthalmologist.
- Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.

#### ADVERSE REACTIONS

In clinical studies, the most frequently reported adverse events (>2%)
were nasopharyngitis, headache, injection site pain, injection site
reaction, upper respiratory tract infection, eyelid edema, eyelid ptosis,
sinusitis, nausea, and blood present in urine.

#### DRUG INTERACTIONS

- Concomitant use of *Dysport* and aminoglycosides or other agents interfering with neuromuscular transmission or muscle relaxants, should be observed closely because effect of *Dysport* may be potentiated.
- Anticholinergic drugs may potentiate systemic anticholinergic effects.
- The effect of administering different botulinum neurotoxins during course of treatment with *Dysport* is unknown.

#### USE IN SPECIFIC POPULATIONS

 $\bullet \quad \textit{Dysport} \text{ is not recommended for use in children or pregnant women.} \\$ 

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, inside the pocket of this folder, or at DysportUSA.com.

#### Sculptra® Important Safety Information

*Indication:*  $Sculptra^{\circ}$  (injectable poly-L-lactic acid (PLLA-SCA)) is indicated for use in people with healthy immune systems for the correction of shallow to deep nasolabial fold contour deficiencies, fine lines and wrinkles in the cheek region, and other facial wrinkles.

Sculptra should not be used by people that are allergic to any ingredient of the product or have a history of keloid formation or hypertrophic scarring. Safety has not been established in patients who are pregnant, lactating, breastfeeding, or under 18 years of age.

Sculptra has unique injection requirements and should only be used by a trained healthcare practitioner. Contour deficiencies should not be overcorrected because they are expected to gradually improve after treatment.

Sculptra should not be injected into the blood vessels as it may cause vascular occlusion, infarction or embolic phenomena. Use at the site of skin sores, cysts, pimples, rashes, hives or infection should be postponed until healing is complete. Sculptra should not be injected into the red area (vermillion) of the lip or in the peri-orbital area.

The most common side effects after initial treatment include injection site swelling, tenderness, redness, pain, bruising, bleeding, itching and lumps. Other side effects may include small lumps under the skin that are sometimes noticeable when pressing on the treated area. Larger lumps, some with delayed onset with or without inflammation or skin discoloration, have also been reported.

Sculptra is available only through a licensed practitioner. Complete Instructions for Use are available at www.SculptraUSA.com/IFU.

#### RESTYLANE FAMILY IMPORTANT SAFETY INFORMATION

The Restylane family of products are indicated for patients over the age of 21, and includes Restylane®, Restylane-L®, Restylane® Lyft with Lidocaine, Restylane® Silk, Restylane® Kysse, Restylane® Refyne, Restylane® Defyne, Restylane® Contour, and Restylane® Eyelight.

#### APPROVED USES

Restylane® and Restylane-L® are for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. Restylane® and Restylane-L® are also indicated for injection into the lips.

Restylane® Lyft with Lidocaine is for deep implantation into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and for cheek augmentation and for the correction of agerelated midface contour deficiencies. Restylane® Lyft with Lidocaine is also indicated for injection into the dorsal hand to correct volume loss.

Restylane® Silk is for lip augmentation and for correction of perioral wrinkles.

Restylane® Kysse is for lip augmentation and for correction of upper perioral wrinkles.

Restylane® Refyne is for mid-to-deep injection into the facial tissue for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

Restylane® Defyne is for mid-to-deep injection into the facial tissue for the correction of moderate to severe deep facial wrinkles and folds, such as nasolabial folds. Restylane® Defyne is also indicated for injection into the mid-to-deep dermis (subcutaneous and/or supraperiosteal) for augmentation of the chin region to improve the chin profile in patients with mild to moderate chin retrusion.

Restylane® Contour is for cheek augmentation and for the correction of midface contour deficiencies.

Restylane® Eyelight is for the improvement of infraorbital hollowing.

Do not use if you have severe allergies with a history of severe reactions

Do not use if you have severe allergies with a history of severe reactions (anaphylaxis), are allergic to lidocaine or gram-positive bacterial proteins used to make hyaluronic acid, prone to bleeding, or have a bleeding disorder. The safety of use while pregnant or breastfeeding has not been studied. Tell your doctor if you have a history of scarring or pigmentation disorders as these side effects can occur with hyaluronic acid fillers. Tell your doctor if you are planning other cosmetic treatments (i.e., lasers and chemical peels) as there is a possible risk of inflammation at the injection site.

Tell your doctor if you're taking medications that lower your body's immune response or affect bleeding, such as aspirin or warfarin, as these medications may increase the risk of bruising or bleeding at the gel injection site. Using these products on gel injection sites with skin sores, pimples, rashes, hives, cysts, or infections should be postponed until healing is complete.

The most common side effects are swelling, redness, pain, bruising, headache, tenderness, lump formation, itching at the injection site, and impaired hand function. Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers, and cases have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own. Serious but rare side effects include delayed onset infections, recurrence of herpetic eruptions, and superficial necrosis at the injection site. The risk of unintentional injection into a blood vessel is small but can occur and could result in serious complications, which may be permanent including, vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. As with all skin injection procedures, there is a risk of infection.

To report a side effect with any Restylane® product, please call Galderma Laboratories, L.P., at 1-855-425-8722.

To learn more about serious but rare side effects and full Important Safety Information, visit www.RestylaneUSA.com.

## GALDERMA

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