GALDERMA

EST. 1981

Dysport®

# Patient Consent Form for Aesthetics Treatment

Last Name: _____ First Name: _____

Last 4 digits of NRIC:_____Gender: _____ Date of Birth: _____

Address: _____ Postal Code: _____

Mobile: _____ Email: _____

**I confirm I have been informed that:**

Dysport® (botulinum toxin type A) uses the toxin produced by the bacteria *Clostridium botulinum*. The toxin weakens the muscles responsible for developing facial-expression lines caused by muscle activity. This muscle relaxation is temporary and gradually wears off.

Each vial of Dysport® contains 500 units of the toxin complex. These units apply to Dysport® only and are not the same for other medicines containing botulinum toxin.

Dysport® (botulinum toxin type A) is licensed for temporarily improving the look of moderate-to-severe frown lines between the eyebrows (glabellar line) and lateral canthal lines (crow's feet lines) in patients below the age of 65 and is injected into the skin to reduce these lines.

**Treatment is not recommended if you are pregnant or breastfeeding.**

After treatment with Dysport®, you should start noticing an improvement within 2–3 days. However, it can take up to 30 days to notice its complete effect. The benefits of treatment usually last between 4 and 6 months, but can vary depending on your individual response.

The most common side effects of Dysport® include headache and injection-related reactions (e.g. redness, swelling, irritation, rash, itching, numbness, pain, discomfort, stinging, bruising, and bleeding). Normally, these reactions are mild-to-moderate, reversible, and occur in the first week after the treatment. There is also a small possibility of a slight drooping of the eyelid or visual problems. Very rarely, botulinum toxin may result in muscle weakness away from the site of injection. Other side effects are listed in the Health Sciences Authority (HSA) approved Patient Information Leaflet (please ask if you have not been given this). If any side effects persist or worsen, or are not listed in the Patient Information Leaflet, you should inform your practitioner as soon as possible. Seek urgent medical help if you have difficulties breathing, swallowing, speaking, or if your face swells up.

Dysport® may cause temporary blurred vision or muscle weakness. If affected, you should not drive or use any machinery.

Dysport® contains a very small amount of albumin, which comes from human blood. It is very unlikely that this could pass on an infection, but it cannot be entirely ruled out.

- I have been fully informed about the risks and benefits of treatment with Dysport®.
- The practitioner has provided me with sufficient information about the treatment, in order to make an informed decision.
- I have been given the opportunity to ask all remaining questions I may have about the treatment and I am happy with the answers provided.
- I have been given the time to consider the treatment and have been informed of alternative treatment options, which also includes no treatment.
- I confirm that I am not pregnant or breastfeeding.
- I have been given the Dysport® Patient Information Leaflet.
- I confirm that I am above 18 and below 65 years of age.

_____ _____

Patient's Signature Date



SG-DYS-2100007

GALDERMA

EST. 1981

I confirm that I have discussed what the procedure is likely to involve, the benefits, and risks of any available alternative treatments (including no treatment), and any concerns of this patient.

Practitioner's/Injector's Signature: _____ Date: _____

Name of Injector: _____ Job Title: _____

Clinic Name: _____ Clinic Address:

## Dysport® Abridged Patient Information Leaflet

Adapted from the HSA-approved Patient Information Leaflet for Dysport®; approved on 31 July 2018.

**What is Dysport®?**

Dysport® is a toxin produced by *Clostridium botulinum* bacteria. The toxin acts on the junctions between the nerves and muscles, preventing the release of one of the chemical messengers called acetylcholine from the nerve endings which would normally cause the muscle to contract. If the messenger is prevented from being released, this results in a weakened muscle and helps to reduce some of the abnormal muscle contractions. It can also be used to prevent muscles which cause frown lines and crow's feet lines from contracting. This muscle relaxation is temporary and gradually wears off. Each vial of Dysport® contains 500 units of the toxin complex. These units apply to Dysport® only and are not the same for other medicines containing botulinum toxin.

**What is Dysport® used for?**

Dysport® is used to improve of the look of moderate to severe frown lines between the eyebrows (glabellar line) and lateral canthal lines (crow's feet lines) in patients below the age of 65.

**Is there any reason for not being given Dysport®?**

You should not be given Dysport® if you have had a previous allergic reaction to botulinum toxin or any of the ingredients.

**Tell the doctor if:**

- You think you are allergic to any of the ingredients contained in Dysport®.
- You have had any unusual reactions such as skin rashes following any previous injection of toxin.
- You are taking any medicines, in particular aminoglycoside antibiotics.
- You have any history of bronchitis, pneumonia and problems with breathing.
- You have problems swallowing.
- You are pregnant or think you may be pregnant or you are breastfeeding your baby. This is because there are increased risks of having toxin injections under these circumstances.
- You bleed easily.
- You have other problems or diseases that affect your muscles e.g. myasthenia gravis.
- You have an infection where the injection is given or if that area is swollen.
- You have had surgery on your face or are likely to undergo facial surgery or other types of surgery soon (if you are considering treatment for glabellar lines or lateral canthal lines).
- You had no significant improvement of your lines after your last treatment (if you are considering treatment for glabellar lines or lateral canthal lines).

**Additional information**

Dysport® contains a small amount of albumin which has been obtained from human blood. The risk of a viral infection cannot be eliminated completely when using human blood or products made from human blood. Dysport® injection depending on the site of injection may lead to weakness and visual disturbances and may temporarily impair ability to drive or operate machinery.

**How will the medicine be given?**

The doctor will make up the injection and give the injection. The doctor will decide where to make the injections and for how long treatment is needed. For temporary improvement of glabellar lines and/or lateral canthal lines, the recommended dose is:

- For glabellar lines: 50 units, injected as 10 units at each of 5 injection sites in your forehead in the area above your nose and eyebrows
- For lateral canthal lines: 60 units, injected as 10 units at each of 6 injection sites in both crow's feet regions

A 12 weeks minimum interval between 2 injection sessions is required. Contact your doctor and seek medical attention immediately if you develop problems with swallowing, speech or breathing. Use of Dysport® for this purpose is not recommended for patients below the age of 18.

**What will happen if I stop taking Dysport®?**

The relaxing effect will eventually wear off and the muscle movements will return to the way they were before treatment.

**What side effects can Dysport® have?**

Along with its desired effects Dysport® may cause unwanted effects because of a weakening of muscles near the injected muscle. Tell your doctor immediately if:

- You have any problems swallowing, breathing or with your speech
- You develop difficulty in breathing with or without swelling of the face, lips, tongue and/or throat, redness of the skin or an itchy lumpy rash (urticaria). This may mean you are having an allergic reaction to Dysport®.

**How often it occurs**

Some side effects may occur in any patient treated with Dysport® whilst other side effects may depend on the condition treated. Make sure you read all the sections that apply to you.

| | How often it occurs |
|---|---|
| Very Common | Occurs in more than 1 in 10 patients treated |
| Common | In less than 1 in 10 patients treated |
| Uncommon | In less than 1 in 100 patients treated |
| Rare | In less than 1 in 1000 patients treated |

**Treatment of any condition (all patients)**

**Common:**

- Bruising or pain around the site where the injection was given
- Generalised weakness
- Tiredness
- Flu-like symptoms

**Uncommon:**

- Itching

**Rare:**

- Skin rashes
- Sudden severe pain and weakness in shoulder and/or arm (neuralgic amyotrophy)

**Temporary improvement of glabellar lines**

**Very Common:**

- Headache
- Redness, swelling, irritation, rash, itching, tingling, pain, discomfort, stinging or bruising at the site of injection

**Common:**

- Tired eyes or dim vision, drooping of the upper eyelid, swelling of the eyelid, watering eyes. Dry eye, twitching of muscles around the eyes
- Temporary facial paralysis

**Uncommon:**

- Eye movement disorder
- Dizziness
- Impaired, blurred or double vision

**Rare:**

- Itchy and lumpy rash (hives)

**Temporary improvement of lateral canthal lines**

**Common:**

- Headache
- Temporary facial paralysis
- Swelling of the eyelid
- Drooping of the upper eyelid
- Bruising, itching, and swelling around the eyes

**If any of the side effects becomes serious or if you notice any side effects not listed in this leaflet, please inform your doctor.**



SG-DYS-2100007

Dysport®