Azzalure - Consent Form

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CLIENT INFORMATION

Full Name:

Address:

Telephone:

Product:

Product Label:

I, ... understand that I will be injected with Azzalure® Botulinum Toxin type A in the area of the glabella muscles to paralyse these muscles temporarily, or in the forehead or crow's feet around the lateral area of the eyes.

Azzalure® Botulinum Toxin type A injection has been approved for the cosmetic treatment of glabellar frown lines only – the wrinkles between the eyebrows.

Injection of Azzalure® Botulinum Toxin type A into the small muscles between the brows causes those specific muscles to halt their function (be paralysed), thereby improving the appearance of the wrinkles.

I understand the goal is to decrease the wrinkles in the treated area. This paralysis is temporary; re-injection is necessary within three to four months. It has been explained to me that other temporary and more permanent treatments are available.

Although the effects of Azzalure® Botulinum Toxin type A can be dramatic, as much as 10% may not respond to treatments for unknown reasons.

The possible side effects of Azzalure® Botulinum Toxin type A include, but are not limited to:

1) Risks - I understand there is a risk of swelling, rash, headache, local numbness, and pain at the injection site. bruising, respiratory problems, and allergic reactions.

2) Infection—Infections can occur, and in most cases, they are easily treatable. However, in rare cases, permanent scarring in the area can occur.

3) Most people have lightly swollen pinkish bumps where the injections went in for several hours or even several days.

4) Although many people with chronic headaches or migraines often get relief from Azzalure® Botulinum Toxin type A, a small percentage of patients get headaches following treatment with Botox for the first day. These headaches can persist for several days or weeks in a very small percentage of patients.

5) Local numbness, rash, pain at the injection site, flu-like symptoms with mild fever, and back pain.

6) Respiratory problems such as bronchitis or sinusitis, nausea, dizziness, and tightness or irritation of the skin.

7) Bruising is possible anytime you inject a needle into the skin. This bruising can last for several hours, days, weeks, or months; in rare cases, the effect of bruising could be permanent.

8) While the local weakness of the injected muscles is representative of the expected pharmacological action of Azzalure® Botulinum Toxin type A, weakness of adjacent muscles may occur because of the spread of the toxin.

9) Treatments: I understand that more than one set of injections may be needed to achieve a satisfactory result.

10) Another risk when injecting Azzalure® Botulinum Toxin type A around the eyes includes corneal exposure because people may be unable to blink the eyelids as often as they should to protect the eye. This inability to protect the eye has been associated with damage to the eye, such as impaired vision or double vision, which is usually temporary. This reduced blinking has been related to corneal ulcerations. Some medications can help lift the eyelid; however, the eye drops are ineffective if the drooping is too significant. These side effects can last for several weeks or longer. This occurs in 2-5 per cent of patients.

11) I will follow all aftercare instructions as I must do so for healing.

We would like to thank NATA (nataonline.co.uk) for their help in verifying that all the consent forms are complete.

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As Azzalure Botulinum Toxin type A is not an exact science, there may be an uneven appearance of the face, with some muscles more affected by the Azzalure Botulinum Toxin type A than others. In most cases, this uneven appearance can be corrected by injecting Azzalure® Botulinum Toxin type A in the same or nearby muscles. However, in some cases, this uneven appearance can persist for several weeks or months.

This list is not meant to include all possible risks associated with Azzalure® Botulinum Toxin type A, as known and unknown side effects are associated with any medication or procedure.

Azzalure® Botulinum Toxin type A should not be administered to a pregnant or nursing woman.

ADDITIONALLY

The number of units injected is an estimate of the amount of Azzalure® Botulinum Toxin type A required to relax the muscles.

I understand there is no guarantee of the results of any treatment.	YES □	NO □
I know that the regular charge applies to all subsequent treatments.	YES □	NO □
I understand and agree that I am responsible for payment for all services rendered.	YES □	NO □

ALTERNATIVE TREATMENTS

Alternative forms of management include not treating the skin wrinkles by any means.

Other treatments or alternative types of surgery, such as a blepharoplasty or face or brow lift, may be used to improve skin wrinkles when indicated.

Other forms of eyelid surgery may be needed should you have intrinsic disorders affecting the function of the eyelid, such as drooping eyelids from muscle problems (eyelid ptosis) or looseness between the eyelid and eyeball (ectropion).

Minor skin wrinkling may be improved through chemical skin peels, lasers, injection of filling material, or other skin treatments, such as topical treatments, LED / PDT treatment, Radio Frequency, and Ultrasound; this is not an exhaustive list.

Risks and potential complications are associated with alternative medical or surgical treatment forms.

I understand that there may be a higher possibility of side effects if I do not follow specific instructions, and I will adhere to these instructions for at least 4 hours from the time of treatment.

THESE INCLUDE:

➢ I will not lie down or bend forward for at least 4 hours after treatment.

➢ I will not manipulate or massage the treated area for at least 4 hours after the treatment.

By signing below, I acknowledge that I have read the informed consent and agree to the treatment with its associated risks.

I hereby consent to perform this and all subsequent Azzalure® Botulinum Toxin type A treatments with the above understood. I hereby release the Nurse Practitioner, the person injecting the Azzalure® Botulinum Toxin type A, and the facility from liability associated with this procedure.

CLIENT DECLARATION

I confirm I have had the opportunity to ask questions, that these have been answered to my satisfaction, and that I freely choose to proceed with my treatment.

Client Signature: _____ Date: _____

Practitioner Signature: _____ Date: _____

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