



Aesthetic Complications Expert Group

Anti-Wrinkle Injections





Patient Information Leaflet

Botulinum Toxin Type A

When considering treatment with **botulinum toxin** we want you to have a safe treatment. Some risks are unavoidable and out of your control. The following information should allow you to know what to expect and what you should ask of your practitioner.

What is Botulinum Toxin Type A?

Botulinum toxin is a naturally occurring protein produced by the bacterium *Clostridium Botulinum*. In a purified form, as is the case with many drugs/medications such as Penicillin, Botulinum toxin is a very safe, effective treatment not only used in cosmetic clinics, but also for a number of medical conditions, including migraine and excessive sweating.

Licensed brands of botulinum toxin A include Botox[®], Azzalure[®], Bocouture[®], Xeomin[®] and Dysport[®]. All botulinum toxins are prescription only medicines (POM) and can only be prescribed by doctors, dentists and nurses or prescribing pharmacists with the prescribing qualification, following a face to face assessment and consultation with the qualified prescriber.

How does it work?

The toxin blocks the transition of chemical messages sent from the nerve to cause the muscle to contract. Without these messages, the muscle stays in a resting state until the 'messengers' recover. This recovery takes approximately 8 to 12 weeks on average.

The aim of this treatment is to significantly reduce the movement of the muscles causing expression lines (dynamic lines). It may not cause the expression lines themselves to disappear completely, this will depend upon the quality of your skin and may take time over a course of treatments. It may not 'completely freeze' the expression, particularly if extreme effort is exerted to make an expression.

Botulinum toxin is not suitable for lines present without expression (static lines), your practitioner will advise you. There may be only a partial reduction in movement this very much depends on the amount administered and location of product placement – This is not a one size fits all treatment and may be tailored to suit your individual requirements and expected treatment outcomes – discuss this with your clinician at the time of consultation.

Does it hurt?

A very fine needle is used and generally this treatment is not painful and can be well tolerated with no anaesthetic.

Ice may be helpful in numbing the skin for nervous patients as well as reducing the risk of a bruise.



Treatment areas

Though widely used in cosmetic medicine and with an extensive evidence base to support safety and efficacy, Botulinum toxin A brands, Botox[®], Azzalure[®] and Bocouture[®] are licensed for the treatment of frown lines; Botox[®] and Azzalure[®] are also licensed for the treatment of crow's feet. All other indications are, for the time being, 'off label', i.e. being used beyond the terms of the original license. Many drugs are routinely used off label. Please discuss with your practitioner if you have any concerns and they will be happy to explain further.

- ✓ Frown Lines
- ✓ Crow's Feet
- ✓ Forehead Lines
- ✓ Bunny Lines
- ✓ Lip Lines
- ✓ Turkey Neck (Neck Bands)
- ✓ Jawline (Nefertiti Lift)
- ✓ Slimming of Jaw Muscles (Masseters)
- ✓ Hyperhidrosis (Excessive Sweating)

Choosing your practitioner

Ensure you know the following information:

- ✓ The full name of the practitioner who is treating you
- ✓ Their qualification (doctor, dentist, registered nurse or other)
- ✓ Contact details (address, telephone and email)
- ✓ An emergency contact number for out of normal office hours



These are essential should you have a complaint or a problem and need to escalate it to any external authority.

Registered nurses, doctors, dentists and pharmacists are accountable to the standards of their statutory bodies, you can check their registration and they must hold indemnity insurance for the treatments and services they provide.

If you are unsure or don't have time to research yourself, Independent Voluntary Registers such as Save Face www.saveface.co.uk or Treatments You Can Trust www.treatmentsyoucantrust.org.uk undertake a verification and inspection process of practitioners who wish to be included on their registers. These registers are themselves accountable to the Professional Standards Authority www.professionalstandards.org.uk.

Checklist

- ✓ Do not book and pay for a particular treatment in advance of meeting the practitioner for assessment and consultation. These treatments are not suitable for everyone, and cannot necessarily achieve the results you want within your budget. It is also important for you to 'interview' the practitioner to make sure you trust them and feel safe with them.
- ✓ Do not feel pressured to make any quick decisions.
- ✓ Do be honest about your medical history; in particular any previous facial surgery as this may alter the anatomy under the skin.
- ✓ Any medications you are taking, some may affect the way the treatment works.
- ✓ Any current illness or long-term conditions that you have.
- ✓ Any recent or planned dental treatments (this may affect the anatomy, or may increase your risk of post treatment infection).
- ✓ Any diagnosed neurological conditions; some may increase your risk of complications and how you recover from them.
- ✓ Do be honest about your expectations
- ✓ Do listen to the practitioner's explanation of possible risks, side effects and complications, previous positive experience does not indicate protection or immunity from the risks described.

Do not schedule your treatment when you have an important event or holiday/trip planned within 4 weeks. Should you have a problem, your practitioner will need to see you in order to provide corrective treatment or advise you.

Before treatment

- ✓ All make up will need to be removed prior to treatment, attend 'fresh faced' if possible. Contamination with makeup can cause infection.
- ✓ Taking the following within 72 hours of treatment may increase your risk of bruising – Alcohol, Aspirin, Ibuprofen, St. John's Wort, Fish oils, Gingko Biloba, Vitamins C and E.
- ✓ Do cancel if you are at all unwell, even minor coughs and colds can increase your risk of post treatment complications.
- ✓ Do contact the clinic to discuss any illness or new medicines prior to attending.

After treatment



Most people are able to continue with normal activities. Some will have some redness, pin-prick marks, possibly minor swelling which should settle within an hour. Bruising may be more apparent the next day and can take up to 10 days to fade. Tenderness should settle within 48 hours. It is possible to suffer a headache or a sensation of tightness or heaviness for a few days following treatment. Pain killers may be taken as required.

After treatment it is expected that you will start to see an improvement within 2 or 3 days. The full result may be judged at 2-3 weeks. You may be invited to attend a review appointment at 2-3 weeks where the success of the treatment may be assessed and adjustments to your personal treatment plan made if necessary.

Results tend to last 3-4 months Movement will begin recovering from 8 weeks. Frequent treatment at intervals of less than 3 months is NOT recommended.

- ✓ Make-up should not be worn for 12 hours' and the skin should be kept clean, with normal cleansing. Do not use cleansing wipes which may irritate the skin.
- ✓ Avoid extremes of heat or cold, vigorous exercise, rubbing or wearing tight hats or headgear the day of treatment.
- ✓ Keep using your expressions, the toxin is attracted to active muscles.

Things to look out for

Please contact your practitioner if redness, tenderness or swelling **worsens** after 3 days, rather than settling. Though some tenderness is to be expected, pain is not and should be reported.

If you suffer any of the following symptoms, which may indicate a serious allergic reaction, seek immediate medical attention:

- ✓ Itching
- ✓ Rash
- ✓ Red itchy welts
- ✓ Wheezing
- ✓ Difficulty swallowing
- ✓ Asthma symptoms
- ✓ Dizziness
- ✓ Feeling faint



If you are at all concerned about symptoms you were not expecting or any that concern you, you should contact the practitioner who treated you and make an appointment to be seen.

If you wish to see someone else, contact your practitioner and ask for a copy of your treatment record and or a referral letter. This detailed information will be important if another practitioner is going to safely help or advise you.

If you suffer any adverse reactions or a poor cosmetic result, it may be that correction is not possible and you will be advised to wait until the muscle recovers and the toxin wears off. All side effects are temporary and reversible as the effects wear off.

If you have suffered a serious side effect, related to the medicine or product used (rather than the technique of the practitioner), you may report to The Medicines and Healthcare Regulatory Authority (MHRA) using The Yellow Card Scheme

Is it safe?

All treatments carry a degree of risk. All risks and complications will be discussed with you at consultation and prior to any treatment being agreed.

Botulinum Toxin should be administered by a healthcare professional with specialist training. Adverse events are uncommon, usually occur within a few days of treatment and are expected to be temporary, usually resolving spontaneously within weeks.

Your practitioner will provide aftercare advice designed to minimise risk and promote speedy recovery from any expected side effects.

Side effects include, but are not limited to:

- ✓ Bruising
- ✓ Swelling at injection sites
- ✓ Redness at injection sites
- ✓ Asymmetry of expression
- ✓ Drooping of the brow, or eyelid
- ✓ Headache or a sensation of 'tightness' or 'heaviness'

Am I suitable for treatment?

Your practitioner will take a detailed medical history and an assessment of your needs and expectations to ensure this is an appropriate treatment for you. This must be a nurse, doctor, dentist or prescribing pharmacist with specialised training, qualified to prescribe.

Except in exceptional circumstances this is not a treatment recommended for those under 25 or over 65.

For best results skin should be in good condition and the target lines not too furrowed. Your practitioner will assess your suitability and advise.

- ✓ Botulinum toxin cannot be given to pregnant or breast feeding women.
- ✓ Not suitable for patients with certain neurological disorders.
- ✓ Not suitable if you are currently taking certain medicines.
- ✓ If you have previously experienced adverse reactions to any botulinum toxin treatment.
- ✓ Treatment is not recommended if you are suffering from any skin infection in or near the treatment area or are unwell in any way (even a cold).
- ✓ If you are taking any medicines which affect bleeding, such as aspirin or warfarin.
- ✓ If you are currently or have recently completed a course of Roaccutane (acne treatment) in the last 18 months.

If you have suffered a serious side effect, related to the medicine or product used (rather than the technique of the practitioner), you may report to The Medicines and Healthcare Regulatory Authority (MHRA) using The Yellow Card Scheme yellowcard.mhra.gov.uk.



Summary Checklist

What to expect

- ✓ To be seen by a doctor, nurse, dentist or prescribing pharmacist for your consultation and assessment
- ✓ To have sufficient time to consider all the information- avoid making hasty decisions
- ✓ To be treated by a doctor, nurse, dentist or prescribing pharmacist
- ✓ A follow up appointment if necessary or desired

Ask questions

- ✓ What is this treatment/product?
- ✓ How does it work?
- ✓ What are the side effects/risks?
- ✓ What are the alternatives I might consider?
- ✓ What results can I expect?
- ✓ What will I look like immediately after?
- ✓ How long will the results last?
- ✓ How many treatments will I need and in what time frame?
- ✓ Are you able to treat complications, should they occur?
- ✓ What happens if I am not happy with the result?
- ✓ Is it painful? How do you minimise pain?
- ✓ What aftercare am I expected to perform?
- ✓ What will it cost and what are the payment terms?

What to check

- ✓ Check the qualifications of a Doctor www.gmc-uk.org, Nurse www.nmc-uk.org, Dentist www.gdc-uk.org and Prescribing Pharmacist www.pharmacyregulation.org
- ✓ Ask to see the unopened box of product/medicine to be used and make a note of it for future reference, should you later see another clinician.

Be Safe

- ✓ Do not proceed with treatment if you do not feel comfortable with the practitioner
- ✓ Do not proceed with treatment if you do not fully understand the information you are given
- ✓ Take the necessary time to make your decisions
- ✓ Ask the practitioner to show you the product in its unopened package prior to treatment
- ✓ Make a note of the practitioner's name and product used for future reference
- ✓ Ask for copies of before and after photographs for your reference
- ✓ Do not have treatment in your home, at 'parties' or exhibitions or in environments that are clearly not clean or appropriate