Consent and consultation form for patients treated with
BOTOX® (Botulinum Toxin Type A)

Name: _____

Address: _____

_____

_____

Postcode: _____

Home Tel: _____

Mobile: _____

Email: _____

Date of birth: _____

BOTOX® (Botulinum Toxin Type A)

Treatment record

Prescribing information can be found at the end of this document

ALLERGAN

Medical history

Please complete the following medical questionnaire

Have you previously received any aesthetic treatments (e.g. laser, peels, dermabrasion etc.) Y ○ N ○

If yes, please give more details

Have you had any dermal filler treatment or botulinum toxin? Y ○ N ○

If yes, which treatment did you receive, what areas were treated and when?

Do you smoke? Y ○ N ○

How many per day?

If 'No', have you ever smoked? Y ○ N ○

When did you give up?

Do you drink alcohol? Y ○ N ○

If "Yes", how many units per week?

Do you take regular exercise? Y ○ N ○

If 'Yes', what type of exercise do you do?

Are you currently receiving any medical treatment? Y ○ N ○

Are you currently taking any dietary supplements or medications? If "Yes", please note them below:

Have you had any previous surgery? Y ○ N ○

If "Yes", please give details:

Have you ever been admitted to hospital? Y ○ N ○

If "Yes", please give details:

Do you suffer from any allergies? Y ○ N ○

If yes, please give details:

Have you suffered from any of the following?

Heart disease/angina	Y ○	N ○	Diabetes	Y ○	N ○
Thyroid problems	Y ○	N ○	Stomach ulcer/colitis	Y ○	N ○
Auto-immune disease	Y ○	N ○	Skin disease (e.g. herpes or acne)	Y ○	N ○
Arthritis	Y ○	N ○	HIV/hepatitis	Y ○	N ○
Asthma/bronchitis	Y ○	N ○	Glaucoma/cataract	Y ○	N ○
Convulsions	Y ○	N ○	Venereal disease	Y ○	N ○
Depression	Y ○	N ○	Bell's/facial palsy	Y ○	N ○
High/low blood pressure	Y ○	N ○	Phlebitis	Y ○	N ○
Facial cold sores	Y ○	N ○	Hypoglycaemia	Y ○	N ○

	Y	N
Are you pregnant or breast feeding?	○	○
Have you a history of severe allergy/anaphylaxis?	○	○
Have you a history of severe allergy/ anaphylaxis to BOTOX® (botulinum toxin type A) or its excipients?	○	○
Do you suffer from myasthenia gravis or Eaton Lambert syndrome?	○	○

If you have any questions about the above please discuss these with your practitioner. If the answer is yes to any of the above, your practitioner may ask for further details. Treatment may be refused if it is not considered in your own interest to proceed.

Advised consent

I confirm I have been informed that:

BOTOX® is indicated for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines); moderate to severe lateral canthal lines (crow's feet lines) seen at maximum smile; moderate to severe crow's feet lines seen at maximum smile and glabellar lines seen at maximum frown when treated simultaneously in adults, when the severity of these lines has an important psychological impact for the patient.

Like all medicines, BOTOX® can have side effects, although not everybody gets them. In general, side effects occur within the first few days following injection. They usually last only for a short time, but they may last for several months and in rare cases, longer. These adverse reactions may be related to treatment, injection technique or both.

Diffusion of botulinum toxin into nearby muscles is possible when high doses are injected, particularly in the neck area.

As expected for any injection procedure, pain/burning/stinging, swelling and/or bruising may be associated with the injection. Speak to your doctor if you are worried about this.

Adverse reactions possibly related to the spread of toxin distant from the site of administration have been reported very rarely with botulinum toxin (e.g. muscle weakness, constipation, difficulty in swallowing, food or liquid accidentally going into the lungs which in some cases may lead to pneumonia). Injection of BOTOX® is not recommended in patients with a history of dysphagia (difficulty to swallow) and impaired swallowing.

The chance of having a side effect is described by the following categories:

Common - More than 1 out of 100 persons and less than 1 out of 10 persons.

Uncommon - More than 1 out of 1,000 persons and less than 1 out of 100 persons.

Injections in the forehead for vertical lines

Common side effects are: Headaches, drooping eye lid, skin redness, localised muscle weakness, face pain.

Uncommon side effects are: Infection, anxiety, numbness, dizziness, inflammation of the eyelid, eye pain, visual disturbance, nausea (feeling sick), dry mouth, skin tightness, swelling (face, eyelid, around the eyes), sensitivity to light, itching, dry skin, muscle twitching, flu syndrome, lack of strength, fever.

Injections in the fan-shaped lines from the corner of the eyes

Common side effects are: Swelling of the eyelid, injection site bleeding and/or bruising.

Uncommon side effects are: Injection site pain and/or tingling or numbness.

Injections in the fan-shaped lines from the corner of the eyes, when treated at the same time as injections in the forehead for vertical lines

Common side effects are: Injection site bruising.

Uncommon side effects are: Injection site bleeding and/or pain.

The following additional side effects have been reported for BOTOX® since it has been marketed: allergic reactions, which can be serious (swelling of the face and airways, difficulty in breathing), loss of nerve supply to/shrinkage of injected muscle, respiratory depression and/or respiratory failure, aspiration pneumonia (lung inflammation caused by accidentally breathing in food, drink, saliva or vomit), chronic disease affecting the muscles (myasthenia gravis), blurred vision, difficulties in seeing clearly, slurred speech, strabismus (squint), numbness, tingling and pain in hands and feet, fainting, pain/numbness/ or weakness starting from the spine, drooping of the muscles on one side of the face, weakness of the face muscles, difficulty moving the arm and shoulder, decreased skin sensation, muscle pain, abdominal pain, diarrhoea, vomiting, loss of appetite, dry mouth, feeling sick, fever, different types of red blotchy skin rashes, feeling generally unwell, speech problems, itching, excessive sweating, hair loss, loss of eyebrows, decreased hearing, noises in the ear, feeling of dizziness or "spinning" (vertigo).

Allergic reactions, difficulties to swallow, speak or breathe, have been reported rarely when botulinum toxin type A has been used for other uses. Visit your doctor immediately if such signs develop after BOTOX® treatment.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

BOTOX® should only be administered by medically qualified physicians with appropriate qualifications and expertise in this treatment and having the required equipment.

Too frequent or excessive dosing of BOTOX® may increase the risk of antibodies in the blood which may lead to failure of treatment with botulinum toxin when used for this and other conditions.

The aesthetic effects of BOTOX® last for an average of 3-4 months but will vary depending on the condition of the skin, area treated, amount of product injected, injection technique and lifestyle factors such as sun exposure and smoking.

After treatment, please avoid extreme facial expressions, alcohol consumption and applying make up for 12 hours. Please avoid extreme sun exposure, UV light, freezing temperatures and saunas for 2 weeks after treatment.

Please ask your treating practitioner for a copy of the BOTOX® package insert.

I confirm that _____ my treating practitioner has:

- Provided me with sufficient information about the treatment detailed overleaf in order to make an informed decision
- Given me the opportunity to ask all remaining questions I may have about the treatment, and has answered them to the best of their ability
- Given me the time to consider the treatment detailed overleaf
- Received the relevant medical history information from me to the best of my knowledge

I therefore consent to receiving the described treatment by my treating practitioner.

Signed: _____ **Date:** _____

Lot number: _____

Date: _____

Notes: _____

Lot number: _____

Date: _____

Notes: _____

BOTOX® (botulinum toxin type A) Glabellar and Crow's Feet Lines Abbreviated Prescribing Information

Presentation: Botulinum toxin type A (from clostridium botulinum), 50 or 100 or 200 Allergan Units/vial. **Indications:** Temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines); moderate to severe lateral canthal lines (crow's feet lines) seen at maximum smile; moderate to severe crow's feet lines seen at maximum smile and glabellar lines seen at maximum frown when treated simultaneously in adults, when the severity of these lines has an important psychological impact for the patient. **Dosage and Administration:** See Summary of Product Characteristics for full information. Do not inject into blood vessels. Botulinum toxin units are not interchangeable from one product to another. Not recommended for patients <18 years. The recommended injection volume per muscle site is 0.1 ml (4 Units). Glabellar Lines: Five injection sites: 2 in each corrugator muscle and 1 in the procerus muscle: total dose 20 Units. Crow's Feet Lines: Six injection sites: 3 in each lateral orbicularis oculi muscle: total dose 24 Units. In the event of treatment failure or diminished effect following repeat injections alternative treatment methods should be employed. **Contraindications:** Known hypersensitivity to any constituent. Infection at proposed injection site(s). **Warnings/Precautions:** Use not recommended in women who are pregnant, breast-feeding and/or women of childbearing potential not using contraception. The recommended dosages and frequencies of administration of BOTOX should not be exceeded due to the potential for overdose, exaggerated muscle weakness, distant spread of toxin and the formation of neutralising antibodies. Initial dosing in treatment naïve patients should begin with the lowest recommended dose for the specific indication. Prescribers and patients should be aware that side effects can occur despite previous injections being well tolerated. Caution should be exercised on the occasion of each administration. There are reports of side effects related to spread of toxin distant from injection site, sometimes resulting in death. BOTOX should only be used with extreme caution and under close supervision in patients with subclinical or clinical evidence of defective neuromuscular transmission and in patients with underlying neurological disorders. Caution in patients with underlying neurological disorder and history of dysphagia and aspiration. Patients should seek medical help if swallowing, speech or respiratory disorders arise. Previously sedentary patients should resume activities gradually. Relevant anatomy and changes due to prior surgical procedures must be understood prior to administration and injection into vulnerable anatomic structures must be avoided. Pneumothorax associated with injection procedure has been reported. Caution is warranted when injecting in proximity to the lung, particularly the apices or other vulnerable structures. Serious adverse events including fatal outcomes have been reported in patients who had received off-label injections directly into salivary glands, the oro-lingual-pharyngeal region, oesophagus and stomach. If serious and/or immediate hypersensitivity reactions occur (in rare cases), injection of toxin should be discontinued and appropriate medical therapy, such as epinephrine, immediately instituted. Procedure related injury could occur. Caution in the presence of inflammation at injection site(s), ptosis or when excessive weakness/atrophy is present in target muscle. Reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. New onset or recurrent seizure occurred rarely in predisposed patients, however relationship to botulinum toxin has not been established. Clinical fluctuations may occur during repeated use. Too frequent or excessive dosing can lead to antibody formation and treatment resistance. It is mandatory that BOTOX is used for one single patient treatment only during a single session. May cause asthenia, muscle weakness, somnolence, dizziness and visual disturbance which could affect driving and operation of machinery. **Interactions:** Theoretically, the effect may be potentiated by aminoglycoside antibiotics or other drugs that interfere with neuromuscular transmission. **Adverse Effects:** See Summary of Product Characteristics for full information on side effects. Based on controlled clinical trial data, the proportion of patients treated for glabellar lines that would be expected to experience an adverse reaction after treatment is 23% (placebo 19%). In pivotal controlled clinical trials for crow's feet lines, such events were reported in 8% (24 Units for crow's feet lines alone) and 6% (44 Units: 24 Units for crow's feet lines administered simultaneously with 20 Units for glabellar lines) of patients compared to 5% for placebo. Adverse reactions may be related to treatment, injection technique or both. In general, adverse reactions occur within the first few days following injection and are transient, but rarely persist for several months or longer. Local muscle weakness represents the expected pharmacological action. Localised pain, tenderness and/or bruising may be associated with the injection. Fever and flu syndrome have been reported. *Frequency By Indication:* Defined as follows*:* Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100). Glabellar Lines (20 Units): *Infections and infestations.* Uncommon: Infection. *Psychiatric disorders.* Uncommon: Anxiety. *Nervous system disorders.* Common: Headache. Uncommon: Paraesthesia, dizziness. *Eye disorders.* Common: Eyelid ptosis. Uncommon: Blepharitis, eye pain, visual disturbance. *Gastrointestinal disorders.* Uncommon: Nausea, oral dryness. *Skin and subcutaneous tissue disorders.* Common: Erythema. Uncommon: Skin tightness, oedema (face, eyelid, periorbital), photosensitivity reaction, pruritus, dry skin. *Musculoskeletal and connective tissue disorders.* Common: Localised muscle weakness. Uncommon: Muscle twitching. *General disorders and administration site conditions.* Common: Face pain. Uncommon: Flu syndrome, asthenia, fever. Crow's Feet Lines (24 Units): *Eye disorders.* Common: Eyelid oedema. *General disorders and administration site conditions.* Common: Injection site haemorrhage*, injection site haematoma*. Uncommon: Injection site pain*, injection site paraesthesia (*procedure-related adverse reactions). Crow's Feet Lines and Glabellar Lines (44 Units): *General disorders and administration site conditions.* Common: Injection site haematoma*. Uncommon: Injection site haemorrhage, injection site pain* (*procedure-related adverse reactions). The following adverse events have been reported since the drug has been marketed for glabellar lines, crow's feet lines and other indications: *Cardiac disorders:* Arrhythmia, myocardial infarction. *Ear and labyrinth disorders:* Hypoacusis, tinnitus, vertigo. *Eye disorders:* Angle-closure glaucoma (for treatment of blepharospasm), strabismus, blurred vision, visual disturbance, lagopthalmos. *Gastrointestinal disorders:* Abdominal pain, diarrhoea, constipation, dry mouth, dysphagia, nausea, vomiting. *General disorders and administration site conditions:* Denervation atrophy, malaise, pyrexia. *Immune system disorders:* Anaphylaxis, angioedema, serum sickness, urticaria. *Metabolism and nutrition disorders:* Anorexia. *Muscoskeletal and connective tissue disorders:* Muscle atrophy, myalgia. *Nervous system disorders:* Bronchial plexopathy, dysphonia, dysarthria, facial paresis, hypoaesthesia, muscle weakness, myasthenia gravis, peripheral neuropathy, paraesthesia, radiculopathy, seizures, syncope, facial palsy. *Respiratory, thoracic and mediastinal disorders:* Aspiration pneumonia (some with fatal outcome), dyspnea, respiratory depression, respiratory failure. *Skin and subcutaneous tissue disorders:* Alopecia, dermatitis psoriasiform, erythema multiforme, hyperhidrosis, madarosis, pruritus, rash. **NHS Price:** 50 Units: £77.50, 100 Units: £138.20, 200 Units £276.40. **Marketing Authorization Number:** 50 Units: 426/0118, 100 Units: 426/0074, 200 Units 426/0119. **Marketing Authorization Holder:** Allergan Ltd, Marlow International, The Parkway, Marlow, Bucks, SL7 1YL, UK. **Legal Category:** POM. **Date of preparation:** June 2015.

Further information is available from: Allergan Limited, Marlow International, The Parkway, Marlow, Bucks SL7 1YL

Adverse events should be reported. Reporting forms and information can be found at **www.yellowcard.mhra.gov.uk**
Adverse events should also be reported to Allergan Ltd. **UK_Medinfo@allergan.com** or **01628 494026.**