INJECTABLE GUIDE
Your reference to the safe use of Muscle Relaxant Injections

By Dr. Lindsey Hooke
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Dr. Lindsey Hooke began her medical journey having studied and become qualified in Medicine and Surgery in 1990 in the UK, after which she moved to Australia in 1991 working in the Department of Surgery at the Gold Coast Hospital. She decided to leave hospital based practice to open a multidisciplinary General Practice which sub specialised in Women’s Health, Dermatology and Aesthetic Medicine. Then her passion led her to study a law degree at Bond University gaining experience in medico-legal practice while working at Blake, Dawson & Waldron. This completed the background skills she felt necessary to run her business and further reinforced her interest in Cosmetic Medicine. After she was given an Associate Professorship at Bond University Medical School she decided to sell her practice to join Dr Douglas Grose at Australian Skin Clinics, to further broaden and develop her cosmetic knowledge and skills leading her to becoming the Medical Director. Keen to begin her own Aesthetic clinic and after completing her Diploma in Aesthetic Medicine, in 2010 Dr Lindsey opened Rejuven8 Cosmetic & Beauty Medispa. A fully qualified Cosmetic Physician and certified Master injector, Dr Lindsey Hooke has also been an active member of the Australasian Society of Cosmetic Medicine (ASCM).
Almost any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. Muscle relaxant treatments involve the injection of a substance called Botulinum Toxin into a localised muscle and this therapeutic product is consequently regulated and governed by the TGA. As a result, it has been categorised as a Schedule 4 preparation.

“The substances are listed in Schedule 4 of the current Poisons Standard and the products are therefore regulated as: Prescription only substances - includes substances, the use or supply of which should be by, or on the order of medical practitioners and should be available from a pharmacist on prescription.” [http://www.tga.gov.au]

“As a Schedule 4 therapeutic preparation the direct advertising of prescription only products to consumers is illegal. Generally, it is an offence under section 42 DL (1) (f) of the Therapeutic Goods Act 1989 (the Act) for a person to publish or broadcast an advertisement about therapeutic goods that contains a statement referring to goods, or substances or preparations containing goods, included in Schedules 3, 4 or 8 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) (the Poisons Standard).” [http://www.tga.gov.au]

The Act broadly defines any advertisement in relation to therapeutic goods as including any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods. [http://www.tga.gov.au]

To comply with the provisions of the Act outlined above this informative ebook cannot specifically refer to the ‘trade names’ of those products containing Botulinum Toxin currently available for therapeutic use in Australia. Instead, I will make reference only to the biochemical product known as Botulinum Toxin or an abbreviated reference to Botulinum Toxin A, BTXA.
WHO IS THE TGA?

WHO THEY ARE
The Therapeutic Goods Administration (TGA) is an Australian regulatory authority focused on therapeutic goods. As a subset of the Department of Health, the TGA is tasked with safeguarding and enhancing the health industry in Australia.

WHAT THEY DO
The TGA implement a range of assessment and monitoring activities to ensure therapeutic goods accessible in Australia are of an acceptable standard. All products are regulated with any available for supply, safe and fit for their intended purpose.

The ultimate goal of the TGA is to ensure all Australians have access, within a reasonable time, to therapeutic advances.

The TGA regulates the supply, manufacturing and advertising of the following products:

- Medicines prescribed by a doctor or dentist
- Medicines available from behind the pharmacy counter
- Medicines available in the general pharmacy
- Medicines available from supermarkets
- Complementary medicines, this includes herbs, vitas and traditional medicines
- Medical devices, including simple devices like band-aids to complex technologies like pacemakers
- Products used to test for various diseases or conditions (in vitriol diagnostic devices) for example blood tests
- Vaccines, blood products and other biologic substances

LINDSEY’S TIP:
THE TGA IS OFTEN BLAMED FOR THE DELAY IN SOME MEDICINES BEING AVAILABLE TO THE PUBLIC BUT THIS DELAY IS NECESSARY TO ENSURE PATIENTS SAFETY
At Rejuven8 Cosmetix we believe that the average member of the public has many unanswered questions pertaining to a number of areas within the cosmetics and beauty industry. Our goal behind writing the e-book was to shed some much needed light on a number of myths, queries and educate consumers in the process.

A few of the motives behind the conception of this e-book include:

- To educate and inform the public on the correct procedures and treatments that should be undertaken by practitioners in the cosmetic industry.
- Test the public’s current understanding of legal and safety protocols.
- Gain a deeper understanding of people’s attitudes towards the cosmetic industry.
- Create a conversation about the complexities and double standards in the industry and what consumers should be aware off.
- Reduce the stigma and risk associated with cosmetic treatments.
- Reduce fraudulent cosmetic treatments being undertaken on innocent customers.
- Advise people of the non-invasive treatments available.
- Assure people that cosmetic treatments are tailored specifically to each individual to complement their natural features.
Botulinum Toxin is produced by a bacterium known as Clostridium Botulinum, which is often present in soil. The toxin in high doses can cause the disease known as botulism, a type of severe poisoning commonly occurring as a result of eating foods containing the bacteria.

Botulinum Toxin is the most potent poison known to man and can be lethal if present in the body at a level of around 0.001mg per kg body weight. It acts as a neurotoxin, blocking the transmission of signals from the brain to a neuromuscular end plate present within muscle fibres. This results in paralysis of the associated muscle fibres and can lead to respiratory failure and subsequent death if present in a lethal dose. Botulinum Toxin occurs in several forms but Botulinum Toxin A (BTXA) is the main type used for therapeutic treatments and cosmetic medicine as it is the most potent subtype with the longest duration of effect.

Medical preparations of BTXA are distributed by a number of pharmaceutical companies and offered under a variety of trade names. There are currently three dominant preparations of BTXA within the market place in Australia:

- Onabotulinum toxin A (Allergan, USA)
- Incobotulinum toxin A (Merz Pharmaceuticals, Germany)
- Abobotulinum toxin A (Ipsen Biopharm, UK)

It is important to note that there are several other subtypes of Botulinum Toxin and several other Botulinum Toxin A products distributed throughout the world in addition to some Botulinum Toxin B products.
1895
Professor Emile Van Ermengem isolated the bacterium Clostridium Botulinum

1928
Dr. Herman Sommer, at the university of California, isolated a purified form of Botulinum Toxin Type A.

1946
Dr. Edward J Schantz succeeded in purifying Botulinum Toxin in type A in crystalline form. He cultured the bacterium Clostridium Botulinum and isolated the toxin.

1949
Dr. Burgen discovered that Botulinum Toxin blocks neuromuscular transmission to muscle fibres.

1950s
Dr. Vernon Brooks discovered that Botulinum Toxin type A blocked the release of acetylcholine from motor nerve endings when it is injected into a hyperactive muscle.

1973
Dr. Alan B. Scott, of Smith-Kettlewell Eye Research Institute, started using Botulinum Toxin type A in animal experiments

1980
Dr. Alan B. Scott used Botulinum Toxin type A for the first time in humans to treat strabismus, a visual problem in which the eyes are not aligned properly and point in different directions. One eye may look straight ahead, while the other eye turns inward, outward, upward, or downward.

1989
Onabotulinum toxin A was approved by the US Food and Drug Administration (FDA) for the treatment of strabismus, blepharospasm, and hemifacial spasm.

Early 1800’s
A German physician Justinus Kerner investigated the possibility of a therapeutic use for Botulinum Toxin, which he called the "sausage poison.

ONABOTULINUM TOXIN A (ALLERGEN, USA)

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ONABOTULINUM TOXIN A
(ALLERGEN, USA)

The clinical use of Botulinum toxin B has been studied, and several products currently are available commercially. Furthermore, the use of Botulinum Toxin F is under investigation in patients who have become resistant to serotypes A and B.

2001
The United Kingdom approved Onabotulinum toxin A for axillary hyperhidrosis (excessive sweating in the armpits). Canada approved Onabotulinum toxin A for axillary hyperhidrosis, focal muscle spasticity, and cosmetic treatment of wrinkles at the brow line.

April 2002
The FDA announced the approval of Onabotulinum toxin A to temporarily improve the appearance of moderate to severe frown lines between the eyebrows.

April 29, 2009
Abobotulinum toxin A was approved for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain.

July 2004
Onabotulinum toxin A was approved to treat primary axillary hyperhidrosis not able to be managed by topical agents, such as prescription antiperspirants.

October 2010
Onabotulinum toxin A injection approved to prevent headaches in adult patients with chronic migraine. Chronic migraine is defined as having a history of migraine and experiencing a headache on most days of the month.

July 2011
Incobotulinum toxin A approved for temporary improvement in the appearance of moderate to severe frown lines in adult patients.

August 2011
The FDA approved Onabotulinum toxin A injection for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition.

The acceptance of Botulinum Toxin A use for the treatment of different chronic pain disorders is growing. However, it has not been approved by the any regulatory bodies for any chronic pain conditions except for chronic migraine.
When considering a muscle relaxant treatment for wrinkles, creases and grooves, it is useful to understand the different types of wrinkles and why they form.

YOUR SKIN

When we are young we have a skin that is rich in hyaluronic acid, collagen and elastin. Our bodies produce these vitally important structures, which consequently give our skin its plump, hydrated firm appearance and allows the skin to stretch and spring back to its original state after movement without any creases being left on the skin.

WHAT HAPPENS AS WE AGE?

As we age these structures are degraded and broken down at a more rapid rate and the body fails to adequately replace this loss. This effect is evident within the skin from the age of 20-30 and becomes increasingly more evident on the skin from 30 years onwards. This degradation and decreased production of vital anti-aging components within the skin is made worse by several factors including sun exposure, ill health, smoking, hormonal changes and dietary deficiencies.

ALL ABOUT WRINKLES

Some of the first wrinkles, creases and grooves to be noticeable on the skin are called Dynamic wrinkles. They are caused by movement of the facial muscles beneath the skin and once the movement is stopped the skin springs back to normal. Later on, Static wrinkles develop, which are caused by a combination of aging, sun damage and or weight fluctuation. They can be a result of folding the skin against a surface e.g. sleeping on your side and creasing the skin against a pillow. Static wrinkles are also a progressive effect from dynamic wrinkles caused by years of movement and creasing of the skin with facial expression. Static wrinkles are clearly visible on the skin at rest when the facial movement has stopped.

So all dynamic wrinkles can progress to static wrinkles and some static wrinkles can form just from skin creasing or general factors associated with aging. It is therefore important to treat dynamic wrinkles early to prevent the future development of static wrinkles. In the majority of cases this treatment will consist of muscle relaxant injections, particularly when treating upper facial dynamic wrinkles e.g. frown lines, forehead creases and crow’s feet around the eyes.
TREATING LINES & WRINKLES

When we smile, frown or laugh we contract muscles in our face into folds of skin that form dynamic wrinkles and lines such as “crow’s feet”, forehead lines or “worry lines”. Over time, these dynamic wrinkles and lines can become deeper and more permanent, being still visible at rest. A simple treatment with Botulinum Toxin A (BTXA) can dramatically soften facial expression lines leaving you looking younger and more refreshed. It causes a temporary relaxation in any muscle it is injected into and stops the muscles from contracting as powerfully, leaving the overlaying skin smooth and unwrinkled. BTXA works only on the specific muscles injected, leaving surrounding muscles to function as usual, and producing normal facial expression without wrinkles. It cannot “freeze” your facial expressions because it only works where you want it to work and there are plenty of other muscles to create natural movement in other, untreated areas.

INJECTING BOTULINUM TOXIN A (BTXA)

BTXA is injected using a disposable syringe with a very fine needle, injecting very precisely into several locations on the face. The pain associated with injections is minimal. No local anaesthetic is required and you can resume normal activities (with some exceptions) immediately after the treatment. Treatments take around 15 - 30 minutes, depending on the number of areas you wish to treat.

After the treatment, it takes 2-3 days for BTXA to begin taking effect and 10-14 days to see the full effect. While each muscle area slowly responds to the BTXA treatment, you may notice some apparent asymmetry or unevenness in movement (e.g. ability to raise one eyebrow higher than the other or more wrinkles on one side of forehead than the other). This should even out over the 14 day period. Occasionally this unevenness persists past 14 days, especially if the muscle in an area treated is stronger than expected or the dose used is a little lower than the dose needed to create the desired result. If this occurs, further BTXA injections may be required to relax those muscles and give an even desired effect in the area treated.
IMPORTANT INFORMATION

It is important to remember that BTXA is a fully metabolisable product. Therefore the result and the duration of that result, is entirely related to YOUR body’s metabolism. Your therapist will advise you of the estimated number of BTXA units required to achieve the best result according to your expectations. However, this is strictly a guide at your first treatment and the dose of BTXA may, and often will, need to be changed from time to time. There are many variables affecting a person’s metabolism and these variables will differ from week to week and month to month. There is also the consideration given to the effect you personally want to achieve from your treatment. Some people desire a marked reduction in muscle movement and yet others require a more conservative reduction in muscle movement. Your therapist should take note of your expectations but there are naturally times when the result needs to be modified to fulfil changes in those expectations.

The effect from BTXA lasts from 2-5 months depending on the individual. The results will wear off progressively after 2-3 months and you will need to repeat the injections 2 - 4 times a year to maintain those results.

LINDSEY’S TIP:
LISTEN TO YOUR COSMETIC INJECTOR AND MAKE SURE HE OR SHE LISTENS TO YOU!
DISCUSSION IS THE KEY TO GETTING THE RESULT ‘YOU’ WANT.
COSMETIC VS. MEDICAL USES FOR BOTULINUM TOXIN A

As you can see in the history of BTXA, regulating bodies have been much quicker in their acceptance of using Botulinum Toxin for medical purposes rather than cosmetic purposes. So how do these treatments differ?

There are some basic differences between the cosmetic and medical uses of BTXA but there are also some medical treatments that create an additional cosmetic effect and vice versa.

COSMETIC TREATMENTS

These treatments involve the use of Botulinum Toxin A to achieve aesthetic changes in facial features. These aesthetic changes are generally made up of:

- **ANTI-WRINKLE TREATMENTS:**
  Reduction in muscle contractions to minimise facial expressions that cause dynamic wrinkles on the skin e.g. crow’s feet around the eyes when you wink.

- **FACIAL RESHAPING TREATMENTS**
  Reduction in muscle contractions to allow another untreated group of muscles to function unopposed, thereby changing the shape of the face e.g. injecting muscles around the chin known as DAO’s to turn up the outer corner of the mouth.
ANTI-WRINKLE TREATMENTS

These treatments involve the use of Botulinum Toxin A to inject the muscles in specific areas to relax those muscles and reduce the visible wrinkling on the skin created by that movement. So which areas are commonly treated?

• FROWN AREA:

One of the nasty expressions which can make you look angry or grumpy when you’re not! It usually has 3-5 muscle components requiring 3-7 individual injections depending on how strong the frown muscle movement is and how visibly severe the frown wrinkles are. Sometimes, additional areas such as around the eyes and forehead are also injected to get the best aesthetic result.

• FOREHEAD:

This is one of the largest muscle groups on the face. It is responsible for raising the eyebrows and creating the ‘washer board’ wrinkles on the forehead. It requires several injections and because of its size it may need more injections at a later date to ensure an even symmetrical result and correct any differences in the position of the eyebrows. The degree of relaxation you want will be discussed before the treatment but some eyebrow movement is a lot nicer than a frozen expressionless forehead. Sometimes injections are also needed around the eyes to get the best aesthetic result.

LINDSEY’S TIP:

This is often the very first place people treat with BTXA

LINDSEY’S TIP:

This is a very tricky area to inject and it is the most common area to need a touch up treatment at 2 weeks
• **EYES:**

There are two circular muscles around the eyes very similar to the one around the mouth. These muscles create the ‘scrunched’ look around the eyes when we squint and form crow’s feet. It is often an area not treated because we quite like this expression and unlike the frown it can be viewed as a ‘happy’ look or ‘laughter lines’. However, if treated it needs several injections in a semi-circular pattern often expending from the mid eyebrow to just beneath the outer corner of the eye. It is possible to reshape the eye to accentuate the outer lateral part of the eyebrow and give this part of the brow a lift if desired. Unfortunately, those annoying wrinkles directly underneath the eye towards the inner corner of the eye are very difficult to treat with any injectable product and probably have to stay for now! As do some of those lower crow’s feet that spread down onto the cheeks, they are really created by smiling and are more commonly described as ‘smile lines’ so we don’t want to change the way you smile because we have ‘chased a wrinkle’ when the anatomy really prevented us from doing so! However, you can use extremely small doses of BTXA to soften these wrinkles without actually injecting deeply within a muscle.

• **MOUTH:**

There is one circular muscle around the mouth which creates a pursed movement creating vertical lip lines on the top and bottom lips, it is injected along the outer edge of the lips with several injections of a low dose to reduce the vertical wrinkles. However, it may slightly alter the way you talk but the effect is very much related to the dose used and people will often get used to it after a few days. Ultimately, you have to weigh up the benefit of the effect you get verses the odd feeling associated with the treatment.
**NOSE:**
There are small muscles around the nose that form a ‘snaring’ or ‘snarling’ expression, creating what we call ‘bunny lines’ on the bridge of the nose. These muscles can be injected with low doses to soften the expression and reduce the appearance of these bunny lines. Injections can also be done between the nostrils to give the tip of the nose a nice ‘lift’.

**CHIN:**
There are a couple of problems that can crop up in the chin area. One is the chin central chin crease. This can develop into a very deep horizontal crease almost creating an isolated lower part of the chin. The second problem is chin dimpling usually seen with sucking movements. Both of these can be treated with BTXA to relax the muscle movement creating the problems.

**DÉCOLLETAGE OR CHEST:**
The neck and décolletage has a large muscle called the Platysma which spreads across the décolletage right the way up to the jawline and lower face. When this muscle contracts fully it can exacerbate the fine creases and lines that form on the décolletage. It can be relaxed by using several very low dose injections spread across the muscle area. This treatment alone will not fully correct deeper creases and crêpey skin on the chest but it will compliment some of the other injectable treatments available to rejuvenate this area.

**LINDSEY’S TIP:**
It’s a good idea to do this with frown treatments.
FACIAL RESHAPING TREATMENTS

Several muscles in the face and neck are responsible for shaping the mid to lower part of the face. There are small muscles which contract to pull the corners of the mouth down and create a ‘sad’ expression. Other muscles used to chew food and grind the teeth can grow to create large bulges on the outer part of the lower face to give the face a square appearance. Some muscles are made up of strap-like bands that extend all the way from the chest to the jawline and when contacted, they enhance jowls and give a sagging look to the lower face and jawline. Many of these muscle groups are working to create a certain shape or feature on the face from a young age. Combine this with natural aging, and a face can develop features that are not flattering and consequently a person can look sad and older than they actuality are. The main purpose in doing these treatments is to relax certain muscles in the face and neck to allow other muscle groups to contract more freely and unopposed, thereby allowing these unopposed muscles to ‘pull’ the face into a different position or shape. The following are the common areas injected to create this reshaping effect on the face:

- **JAWLINE:**
  
  There are quite a few muscles involved in creating the shape of the lower face and jawline. Most of the muscles causing problems such as jowls and downturned mouths are those that pull down the lower face i.e. the ‘depressor’ muscles. These can be individually injected to relax them and allow the muscles that pull the lower face up i.e. the ‘elevator’ muscles to work more freely and unopposed. As you can imagine, the result is to encourage the corners of the mouth to turn upwards and to soften the appearance of jowls. Excessive jowls and ‘dropping’ of the face with aging can lead to a previously oval or round face becoming a rectangular or square face. Once again this is made worse by the depressor muscles of the lower face together with those in the neck. The face can be reshaped by injecting areas where the neck muscles attach to the jawline as well as those mentioned above.

**LINDSEY’S TIP:**

**THESE ARE GREAT TO SOFTEN JOWLS AND PREVENT ‘DOWN TURNING’ AT THE CORNERS OF THE MOUTH.**
**NECK:**

The neck has a large muscle called the ‘Platysma’ which forms bands of muscle that can give you a ‘frilly lizard’ look on the outer part of the neck when you contract them. The muscle goes from the chest all the way to the jawline and lower face. It pulls the jaw down and is usually more prominent in thinner people or those who regularly exercise. These can be relaxed to give a softer look to the neck area and avoid too much pulling on the lower face and jawline. It requires quite a high dose but it produces a really nice reshaping effect on the lower face and jaw. It is also possible to treat the bands going from the chin to the neck (we know them as the ‘turkey neck’) but if too much BTX A is used and injections are placed in the wrong areas it may cause some weakness in swallowing actions. When the muscles bands of the neck are relaxed using BTXA, you may feel some slight weakness in being able to tilt the head forwards. The majority of people do not feel this effect but typically with some gym exercises e.g. sit ups and abdominal crunches it may be more noticeable.

**RESHAPING FACE TO SOFTEN A SQUARE OR ROUND SHAPE TO AN OVAL SHAPE:**

The cheek muscles known as ‘Masseter muscles’ are responsible for some of the chewing actions in the face. If they are large bulky muscles, they give the face a square shape with a broad square jawline. However, it is possible to relax these muscles using several injections into each cheek. The dose per cheek can vary and the effect will need to be checked after 2 weeks to see if a sufficient relaxation has been achieved. At that time further injections may be needed. Masseter muscles can grow to be quite visible on the face. If you clench your teeth and feel the sides of your face you can feel the muscles bulge out. They can make the face look more square and are often quite big in some people of Asian heritage e.g. China. Therefore, relaxing these muscles can make a square shaped face appear more oval in shape and this can be a very desirable affect in some nationalities.
• NEFERTITI FACE LIFTING:

This combines the above treatments to achieve a mini face lift and a more oval shape to the lower face with a smoother jawline. There are quite a few ‘depressor’ muscles involved in creating the shape of the lower face and jawline. These include the small muscles that pull the corners of the mouth down together with the large Platysma muscle that runs upwards from the chest and attaches to the jawline. These muscles need to be sufficiently relaxed using BTXA to allow the ‘elevator’ muscles to work unopposed and create a lifting effect on the lower face. To achieve this effect, several injections of BTXA are done along the jawline, around the corners of the mouth and down the visible neck bands extending to the chest. It may also be necessary to inject BTXA into the Masseter muscles of the cheeks to soften any bulging visible on the face when these muscles are contracted, thereby altering the shape of the face from a blunt square appearance to a more oval appearance. This combination treatment is called the Nefertiti lift as the result can resemble the elongated oval shaped face Nefertiti was renowned for having. This treatment involves quite a few injections and a high dose of BTXA is needed so be aware of the increased cost in achieving this effect. Having said that the effect of this treatment is virtually a mini face lift and it looks fantastic.
MEDICAL TREATMENTS

There are several specialised treatments involving the use of BTXA including treatments for cerebral palsy, involuntary neck spasms, blepharospasm, strabismus and cervical dystonia. I will not cover the details relating to these treatments. Instead I will briefly cover those medical treatments that can be performed in a cosmetic practice environment:

• **BRUXISM & JAW CLENCHING:**

The cheek muscles known as ‘Masseter s’ are responsible for some of the chewing actions in the face. Some of us clench our jaw and grind our teeth when under stress and these muscles help us do that too. Interestingly jaw clenching is caused by the action of the muscles and this in turn makes the muscles grow, which causes more jaw clenching. It is a vicious circle of events. However, it is possible to relax these muscles using several injections in each cheek. The dose per cheek can vary and the effect will need to be checked after 2 weeks to see if a sufficient relaxation has been achieved. At that time further injections may be needed. Masseter muscles can be quite visible on the face. If you clench your teeth and feel the sides of your face you can feel the muscles bulge out. They can make the face look more square and are often quite big in some people of Asian heritage.

**LINDSEY’S TIP:**

THIS SIMPLE TREATMENT COULD SAVE YOU $$$ AT THE ORTHODONTIST
• **HYPERHIDROSIS OR EXCESSIVE SWEATING:**

Is a common disorder affecting many people. Palmar hyperhidrosis or sweaty palms and axillary hyperhidrosis are the most common forms of hyperhidrosis, causing excessive sweating of the hands and armpits. Hyperhidrosis can also cause excessive foot and facial sweating. Sweating is often uncontrollable, embarrassing and not anticipated. Normal sweating is needed for thermal regulation however in people suffering from hyperhidrosis, sweating exceeds the body’s need for physiological thermal regulation. Hyperhidrosis is an inherited problem that has been seen in almost every ethnic group. People don’t get used to living with hyperhidrosis but they continue to suffer throughout their lives from it. It is thought that hyperhidrosis is a result of over activity of the sympathetic nervous system. Hyperhidrosis can have severe physiological consequences such as cold and clammy hands, dehydration, and skin infections secondary to maceration of the skin. It can also have devastating emotional effects on one’s individual life. It is a medical condition with severe negative psychological consequences. Unfortunately friends, relatives of affected individuals and even most doctors usually do not understand the tremendous negative impact that this condition can have on one’s life. Fortunately with the recent advances in medicine, many forms of treatment are available to treat hyperhidrosis. Topical antiperspirants, BTXA injections and surgery (Endoscopic thoracic sympathectomy or ETS) are some methods used to manage or treat hyperhidrosis. Muscle relaxant injections consisting of BTXA, normally used to help reduce the wrinkles on the face can also work to stop sweating. These injections have been widely used for the treatment of hyperhidrosis, especially in the underarms, face and scalp or palms or underneath the breasts. It can also be used in the palms and feet, but it is more painful to inject in this area and may require some form of anaesthetic. The underarms and scalp don’t tend to be too painful and can often be done with just local anaesthetic cream or ice. Muscle relaxant injections work by stopping the nerve signal to the sweat glands in the area it is injected into. The underarms are the most common area treated by muscle relaxant injections. Usually a large dose is used for this area and often this treatment will last up to 8 months depending on the severity of the problem. There are no specific side effects from this treatment.
WHAT ARE THE ‘UNITS’? WHY DO SOME PRACTICES CHARGE FOR ‘UNITS’ AND OTHERS CHARGE FOR ‘AREAS’?

What are the ‘units’ referred to in a muscle relaxant treatments and why do some practices charge for ‘units’ and others charge for ‘areas’?

OK so this can be a very confusing topic. What are ‘units’? Why do some clinics charge for muscle relaxant injections according to ‘areas’? Why does the number of units needed vary from clinic to clinic? How can it cost the same for my friend when she had more wrinkles than me? Is there more than one product available to relax muscles?

This is actually very difficult to explain and even when I was considering how to structure the billing at my own clinic, I pondered over the decision of whether to charge for ‘units’ or ‘areas’ for a very long time!!

I will try to make it very simple and explain it all in sections.

PACKAGING

Let’s start with how BTXA is packaged. OK so there are currently 3 main competing companies in Australia. Both produce BTXA and for government restriction reasons stated above, no one can mention their trade names. These companies package BTXA in 3 different forms in small bottles and yes, they do have to be ‘reconstituted’ i.e. saline (salt water) has to be added to the bottles to mix the BTXA into an injectable liquid form. Of course, each company specifies the exact amount of saline that is to be used for this process and I am not going to get into any discussions about issues of over diluting, that is for you to debate amongst yourselves.

Now the three different bottles hold a different ‘number of units’ of BTXA, two of them (Onabotulinum toxin A & Incobotulinum toxin A) holds 100 Y units and the other (Abobotulinum toxin A) holds 500 Z units. That’s the easy bit! Where it gets more complicated is the comparison of the ‘strengths’ of each product. One thing to remember is that the ‘unit’ mentioned above in relation to each of the two products is completely different. It is a measurement but it is not a comparable measurement of effect between the two products. The effect of 1 Y unit is different to the effect of 1 Z unit. So if you are not already confused I will carry on!
**KNOW YOUR PRODUCTS**

OK so we have 3 different company products that are the same i.e. all contain a subtype of BTXA and they are both measured in ‘units’ but these measurements are totally unrelated. Now, as clinicians we have 3 products we can use that ultimately do the same thing i.e. relax muscles but we now need some way of calculating what dose of each product we use in our injections to achieve the same result from each of the 3 products. Now we could and probably should just treat each one as a separate product in its own right e.g. in the same patient - 10 Y units is used to relax the frown and 18 Z units can also be used to relax the frown to the same degree. But this creates some difficulty in having two different billing structures for the 3 products and we all like some ‘uniform’ consistent way of working out what we have spent and what we have got in return for our money.

How we as clinicians get around this problem, is to find out what the comparative strengths of effect are for 1 unit of the 3 products. Now, we are informed by the companies that 1 Y unit of Onabotulinum toxin A and Incobotulinum toxin A is equivalent in its effect to 2.5 Z units of Abobotulinum toxin A. So if the ‘unit’ is a measurement of comparable effect and the bottle of reconstituted Onabotulinum toxin A or Incobotulinum toxin A contains 100 Y units, the bottle of reconstituted Abobotulinum toxin A (containing 500 Z units) contains 200 Y units in comparison when looking at comparable ‘effect’. So, 1 Y unit of Onabotulinum toxin A and Incobotulinum toxin A = 2.5 Z units of Abobotulinum toxin A in relation to its effect on the muscle and for completeness 1 Z unit of Abobotulinum toxin A = 1/2.5 Y units of Onabotulinum toxin A and Incobotulinum toxin A in relation to its effect on the muscle (i.e. 0.4 Y units).

Later on I will discuss how this impacts on the price you are paying for BTXA treatments.

**LINDSEY’S TIP:**

THIS IS VERY CONFUSING AND SOME CLINICS USE THIS DIFFERENCE IN VERY CLEVER (AND DECEIVING) ADVERTISING - SO BUYER BEWARE OF THE OFFER THAT SEEMS TOO GOOD TO BE TRUE!
It is important to be aware that, as stated above, Botulinum toxin A is a Schedule 4 restricted drug in accordance with TGA categorisation and as such it can only be prescribed by a registered doctor. Consequently, only a registered doctor can hold a contract with a supplier to stock Botulinum Toxin within a practice.

**INTRO**

The following press release from the Australasian College of Aesthetic Medicine features the recent case of a Sydney cosmetic medicine nurse who was deregistered for injecting patients with restricted injectable drugs without adequate supervision.

**SUMMARY**

This case should act as an eye opening experience for cosmetic patients with many unaware that the administration of restricted injectables and dermal fillers is a medical procedure and therefore must be medically supervised.
Main points to take from the press release:

- All cosmetic injectable products are schedule 4 drugs meaning they can only be supplied by a registered doctor. Following an appropriate consultation, injections should be performed by a registered nurse who is appropriately licensed and trained within a supervised environment with a qualified doctor present at the clinic.

- Hair dressing salons, beauty salons and private homes are not medical environments.

- Know exactly what you are being injected with and ensure the provider is correctly administering only FDA/TGA approved products purchased within Australia.

- A nurse who administers Schedule 4 - Full registration with the Nurses and Midwives Board.
- A current certificate in cardiopulmonary resuscitation and competence to manage emergencies.
- Appropriate training in safety and sterility protocols relevant to injections.
- A record of how and where the S4 drug was administered, and the exact dosage.
WHO SHOULD NOT HAVE MUSCLE RELAXANT TREATMENTS?

Contraindications to having muscle relaxant treatments
Apart from hypersensitivity to botulinum toxin A, the contraindications include:

- Neuromuscular disorders such as myasthenia gravis, Lambert-Eaton-Rooke syndrome
- Drugs with an effect on neuromuscular conduction (e.g. muscle relaxants of the tubocurarine type) may enhance the effect
- Cautious treatment with anticoagulants such as Warfarin
- Drugs such as aminoglycoside antibiotics (gentamicin, spectinomycin, tobramycin, netilmicin, amikacin)
- Allergy to the active substance or the additives
- Active infection in or closely associated to the area being treated
- Coagulopathies
- There is no research to support my own opinion but I believe that Botulinum toxin A should not be used during pregnancy or while actively breastfeeding
WHAT ADVERSE EVENTS CAN OCCUR AFTER HAVING A MUSCLE RELAXANT TREATMENT?

Remember that the effects of BTXA are temporary. Any adverse effects that occur will wear off over a few weeks.

- Slight redness, bruising or swelling at the injection site which will resolve spontaneously.
- Mild headache and local tenderness – May last 48 hours and may require pain killing medication.
- Altered position of the eyebrow (raised, flattened or drooping) – in some circumstances, your therapist can correct or improve this by injecting further doses of Botulinum Toxin A or by prescribing eye drops. In the majority of cases this will resolve spontaneously over time.
- Drooping of the upper eyelid (eyelid ptosis) – caused by a small amount of BTXA moving into the muscle of the upper eyelid, very rare (1 in 5000 patients). It may be improved with eye drops and will resolve spontaneously.
- Very rarely, after several treatments, some patients become resistant to the drug i.e. it no longer works effectively.
- Heaviness of the eyebrows – occurs in some older patients because of the poor tone of their muscle. A lower more conservative dose may be injected to prevent this from happening and a further treatment done within 4-6 weeks.

LINDSEY’S TIP:
CONTACT YOUR COSMETIC INJECTOR ASAP IF ‘ANY’ UNWANTED EFFECTS OCCUR AND MAKE SURE HE/SHE GIVES YOU AFTERCARE INSTRUCTIONS ONCE THE TREATMENT IS COMPLETED.
HOW TO MINIMISE THE POSSIBILITY OF AN ADVERSE EVENT AND MAXIMISE THE EFFECT OF THE TREATMENT?

What should you do before or after a muscle relaxant treatment to minimise the possibility of an adverse event and maximise the effect of the treatment?

The following instructions will maximize the benefit of this treatment and reduce the possibility of any adverse effect:

• Maximise facial activity for half an hour after treatment by frowning and squinting etc to encourage binding of the Botulinum Toxin A.

• Using skincare and applying makeup is not a problem if gentle patting is used but DO NOT massage or rub the area treated for 24 hours.

• Avoid lying face down e.g. on massage table for 24 hours.

• DO NOT lie down for 3-4 hours.

• DO NOT wrap towels around wet hair after showers for 24 hours.

• Avoid waxing, massages or other facial treatments on treated areas for 2-3 days

• Avoid wearing any accessories (e.g. hats, sunglasses) that may rub the area treated for 24 hours.

• Avoid hot water and use tepid water to wash the face for 24 hours.

• Do not go to a Gym or undertake strenuous exercise for 24 hours.

• Avoid excess sun exposure, solarium use or spa baths for 24 hours.
### 2013 TOP 10 COSMETIC SURGERY COUNTRIES

1. The United States of America  
2. Brazil  
3. Mexico  
4. Germany  
5. Spain  
6. Colombia  
7. Italy  
8. Venezuela  
9. Argentina  
10. Iran

### 2012 TOP FIVE COSMETIC MINIMALLY INVASIVE PROCEDURES

<table>
<thead>
<tr>
<th>Procedure</th>
<th>2012 Count</th>
<th>Change from 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botulinum Toxin Type A</td>
<td>6.1 Million</td>
<td>Up 8%</td>
</tr>
<tr>
<td>Soft Tissue Fillers</td>
<td>2 Million</td>
<td>Up 5%</td>
</tr>
<tr>
<td>Chemical Peel</td>
<td>1.1 Million</td>
<td>Up 2%</td>
</tr>
<tr>
<td>Laser Hair Removal</td>
<td>1.1 Million</td>
<td>Up 4%</td>
</tr>
<tr>
<td>Microdermabrasion</td>
<td>974,000</td>
<td>Up 8%</td>
</tr>
</tbody>
</table>
DID YOU KNOW?

- Australians spend 40% more per capita than American counterparts at $454,500 per ten thousand people, compared to $328,000 per ten thousand for the USA. *At the time of writing the two currencies were roughly at parity.

- Australians spend around $300 million a year on anti-wrinkle injections.

- In 2010, Australians underwent 1.5 million injections of Botox and similar drugs.

EUROPE

The value of UK cosmetic procedures was worth £2.3 billion in 2010 and estimated to rise to £3.6 billion by 2015. The report also stated that non surgical procedures account for 9 out of 10 procedures and 75% of the market value.
These statistics are taken from the Rejuven8 ‘What Women Want’ survey 2014.

“We structured the questions and flow of the survey to deliver data that will prove useful to my team and woman across Australia. Our aim is to discover how woman feel about themselves, why they have beauty treatments, how often and what they ultimately want out of a trip to a beauty of cosmetic clinic,” - Dr Hooke said.

The goal of survey was to uncover what women really understood about the beauty industry and in-particular injectable treatments. The survey had an amazing response with many women embracing it as a way to express their feelings about the beauty industry and we were shocked by the responses which showed a lack of knowledge about treatments people were undertaking.

1. DO YOU KNOW THAT BOTULINUM TOxin IS A POWDER THAT MUST BE MIXED WITH A SALINE SOLUTION BEFORE USE?
   
   YES =  
   NO =

2. DO YOU KNOW THAT MANUFACTURERS RECOMMEND BOTULINUM TOxin BE MIXED WITH A SPECIFIC VOLUME OF 2.5ML?
   
   YES =  
   NO =

3. DO YOU BELIEVE THAT SOME PROVIDERS WOULD INCREASE THIS AMOUNT TO MAKE MORE PROFIT? (I.E. CAN TREAT MORE PEOPLE OR REDUCE PRICE)
   
   YES =  
   NO =
So you should always choose an injector who has all of the following qualifications and a practice fulfilling the following requirements:

- Full current unrestricted medical registration with the Medical Board within the state
- Full current unrestricted registration with the Nurses and Midwives Board
- Advanced cosmetic medical training preferably with specialised formal qualifications relating to cosmetic medicine
- An in depth and advanced knowledge of facial anatomy and physiology of Botulinum Toxin
- A high level of experience in providing muscle relaxant treatments with written certificates from the relevant companies clearly visible within the practice to ensure that the injector has been certified as competent in providing those treatments
- Treatments are performed in a clinical cosmetic practice focusing purely on aesthetic procedures to ensure a hygienic medical environment that complies with requirements for storage and provision of Botulinum Toxin injections
- The injector should be open and honest about their experience, knowledge and skills relating to muscle relaxant treatments
- A clear knowledge of relevant medical conditions, side effects and contraindications relating to the giving of muscle relaxant treatments
- A registered doctor should always be available in the practice and a nurse injector should have a standing order from the registered doctor authorising him/her to inject Botulinum Toxin

GETTING THE BEST VALUE

While a BXTA treatment is affordable for most patients, it will some financial investment. Be careful unfortunately, many deals are in fact too good to be true.
IS THIS THE RIGHT TREATMENT FOR YOU?

This will markedly reduce the facial movements that create dynamic wrinkles (wrinkles on the skin created by movement of the underlying muscles) and ultimately over time with further treatments it will improve static wrinkles left on the skin after the movement has stopped. However, it certainly isn’t a ‘fix all’ solution.

And it is vitally important that your injector sits down and consults you fully on the pro’s and con’s of a muscle relaxant treatment to address your concerns and outline a treatment plan to include this any other relevant treatments to help you achieve your desired result.

Know the positives and negatives for having a muscle relaxant treatment:

- It is TGA approved for treating the glabella area (frown lines) but it’s ‘off label’ use to treat forehead, nose, lips, eyes, gummy smiles, jawline, chin, neck bands, décolletage and masseter’s are equally effective.

- Botulinum Toxin is best for treating dynamic wrinkles created by repetitive muscle movement. It works by immobilizing the responsible muscles. Other injectable treatments and the use of various forms of equipment are usually more effective for sagging skin or static wrinkles resulting from loss of skin elasticity.

- Results usually start to 2-3 days after the injections and reach a peak of action 10-14 days after treatment. Results last 2-5 months in most patients and after that, you will need to repeat the treatment.

- If you are unhappy with your results, you will have to wait approximately this long for its effects to fade.

- Muscle relaxant treatments can be used preventatively, but shouldn’t replace healthy lifestyle habits that can also postpone aesthetic effects of aging.

LINDSEY’S TIP:

BE SURE THAT A MUSCLE RELAXANT TREATMENT IS THE RIGHT TREATMENT TO ADDRESS YOUR PARTICULAR CONCERNS. BOTULINUM TOXIN INJECTIONS ARE GREAT FOR RELAXING MUSCLES IN SPECIFIC AREAS ON THE FACE AND NECK.
WHY THE PRICE DISPARITY IN THE MARKET
(CHOOSING UNITS OVER AREAS)

OK so we now know how the effects of the two products compare in terms of how many ‘units’ of each product is needed to achieve the same result. Next, we have to figure out how to charge for these products.

Once again, we could just charge differently for each product but this is confusing. Some clinics just avoid this whole issue of number of units and comparative units by charging a certain amount ‘per area’ and then using a fixed amount of whichever product they want.

But what if the wrinkles on your forehead are much less than the wrinkles on your friend’s forehead? Why should you pay the same as her? Well you shouldn’t! No two people are alike, even identical twins can have very different patterns of wrinkles.

So if you are actually getting fewer doses than her wouldn’t you be better off just paying by the unit?

Ultimately, that argument was the reason why I decided to charge people by the unit and not by the area. It gives me a method of ensuring a very ‘individual’ treatment and it gives my clients a precise way of knowing exactly what dose is needed for their particular problem. It also gives them a method of judging how competitive my prices are and if they do decide to move on to another clinic they can stipulate the number of units they have needed in the past to treat the same problem. I have to admit, I love seeing new clients that have had treatments before using this method.

They know the number of units used to treat a particular problem and I then have a baseline to work with. Nice and simple! Just remember to find out though, whether the units are measured according to company Y or company Z e.g. did you have 20 product Y units or 50 product Z units (an equivalent effect would be achieved from both these...
ENHANCING YOUR NATURAL BEAUTY

As you would imagine having practiced in the aesthetic industry for more than 20 years, Dr Lindsey discovered that to preserve your beauty there is essentially 8 key steps, hence the creation of Rejuven8 Cosmetix.

The first and simplest step involves simply arranging a specialised cosmetic consultation to *discover* your natural beauty and discuss an individually tailored plan to suit your individual needs. At Rejuven8 Cosmetix we pride ourselves on listening to everything you have to say and identifying the best way we can work together to achieve the best possible result. Discovering your natural beauty may be as simple as highlighting your naturally beautiful features and letting you know what ‘not to do’ - we love to give clients advice and will gladly spend an hour doing so without the client spending a single cent.

The second step is to *maintain* your natural beauty. At Rejuven8 Cosmetix we will advise you on the correct skin care to use based on a complete assessment of your skin type, general health and consideration of any particular issues you are experiencing.

The third step is to *replenish* your natural beauty, this involves the use of cosmetic beauty treatments, microdermabrasion, peels and the infusion of potent vitamins
and serums to nourish your skin and help improve minor imperfections and textural problems. Some injectable treatments can be performed at this stage to deeply hydrate the skin.

The fourth step is to ‘enhance’ your natural beauty. This stage involved the more intensive use of cosmetic injectable treatments including muscle relaxant injections and various forms of soft tissue enhancements with temporary, semi-permanent and permanent dermal and contour fillers.

The fifth step is to ‘rejuvenate’ your natural beauty. These treatments largely involve the use of cosmetic technologies including lasers, IPL and needling devices.

The sixth step is to ‘restore’ your natural beauty. This stage concentrates on the correction of specific issues on the skin and involves the use of vascular lasers, skin tightening technologies and collagen stimulating treatments.

The penultimate step is to ‘define’ your natural beauty with the use of cosmetic colour tattooing otherwise known as permanent colour pigmentation. This can be used to recreate eyebrows and redefine lip borders and lip colouring. It is also a successful treatment to camouflage scarring on the skin.

The final eighth step is to ‘prolong’ your natural beauty. The team at Rejuven8 Cosmetix will develop a treatment plan specifically designed to prolong the results you have obtained in complete harmony with your natural features so that you can ‘Love The Way You Look’ for many years to come!
ABOUT REJUVEN8 COSMETIX

A key aspect of Rejuven8 Cosmetix’s success is the expert team assembled by Dr Lindsey having brought together leading practitioners from the cosmetic industry, helping make Rejuven8 one of the most experienced teams on the Gold Coast.

Totalling well over 50 years of experience in providing cosmetic treatments and beauty therapy services, Rejuven8 Cosmetix aims to offers all its clients' options for maintaining and enhancing their physical appearance with subtlety and professionalism. Using only state-of-the-art technology and products combined with expert precision, guarantees all aesthetic procedures at Rejuven8 Cosmetix are performed safely with minimal downtime to achieve natural looking results. As an experienced team of cosmetic practitioners we remain acutely aware of the concerns people may have when considering treatments and you can rest assured at Rejuven8 we pride ourselves on achieving beautiful, natural enhancements that work in perfect harmony with your natural features. At the end of the day Dr Lindsey and the entire Rejuven8 team want nothing more than you to ‘Love The Way You Look’ because with their experienced use of non-invasive cosmetic treatments, we can grow older, be beautiful and still retain that natural look!
REFERENCES


Disclaimer: “This Injectable Guide is a ‘guide’ to injectables and is no way meant to influence a decision. The information provided is aimed to help people make an informed decision when choosing an injectable treatment. Everything inside the guide is purely based from Dr Lindsey’s extensive skills, understanding, experience and knowledge within the cosmetic industry. Combined with valuable data and statistics developed through an in-depth survey targeted at understanding consumers knowledge.”
<table>
<thead>
<tr>
<th>QUESTIONS</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>My treatment will be carried out:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In a medical/cosmetic practice</td>
<td></td>
<td></td>
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<tr>
<td>In a practice that has a supervising doctor based at that practice</td>
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<td></td>
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<tr>
<td>The injecting and/or supervising DOCTOR is certified:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>By the relevant Medical Board relating to the State in which he/she practices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The injecting and/or supervising DOCTOR is/has been a member of one or more of these groups:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cosmetic Physicians Society of Australasia (CPSA)</td>
<td></td>
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<tr>
<td>Australasian Society of Aesthetic Plastic Surgery (ASAPS)</td>
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<tr>
<td>Australasian College of Aesthetic Medicine (ACAM)</td>
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<td></td>
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<tr>
<td>Australian Society of Plastic Surgeons (ASPS)</td>
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<td></td>
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<tr>
<td>Australasian Society of Cosmetic Medicine (ASCM)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If a nurse is injecting all of these things are true:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The nurse is a Registered Nurse</td>
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<tr>
<td>The nurse is not an Enrolled Nurse</td>
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<td></td>
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<tr>
<td>The nurse is registered at the time she performs my treatment</td>
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<tr>
<td>The nurse has certificates displayed/available showing she is competent to perform injectable treatments</td>
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<tr>
<td>The nurse is supervised/authorised to perform injectable treatments by a Doctor whose specialty is defined above</td>
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<tr>
<td>There is a doctor permanently based at the medical clinic whose speciality is defined above to supervise/authorise the nurse to perform my treatment</td>
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<tr>
<td>Before having my injectable treatment:</td>
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<tr>
<td>I can have a consultation with a nurse/doctor who fulfils the requirements defined above</td>
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<tr>
<td>I am assured that the products to be used are TGA approved</td>
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<tr>
<td>All risks and benefits of the treatment have been clearly explained</td>
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<tr>
<td>Written information about my treatment is available before the treatment is performed</td>
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<tr>
<td>I can see relevant before and after photos of my treatment</td>
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<td></td>
</tr>
<tr>
<td>My nurse/doctor will give me written instructions after my treatment is done</td>
<td></td>
<td></td>
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<tr>
<td>My medical/cosmetic practice has a contact phone number if I need advice after my treatment</td>
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</table>