BOTULINIM TOXIN INJECTIONS FOR USE IN AESTHETICS

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Information delivered to : **Doctor :**

Patient's name :

Date :

This document has been formulated under the authority of the French Society of Plastic Reconstructive and Aesthetic surgery (*Société Française de Chirurgie Plastique Reconstructrice et Esthétique - SOFCPRE*) to complete the information that you received in your first consultation with your Plastic Surgeon. It aims to answer all the questions that you might ask, if you decide to undertake botulinic toxin.

The aim of this document is to give you all the essential information you need in order to make an informed decision, with full knowledge of the facts related to this procedure. Consequently, we strongly advise you to read it carefully.

● *DEFINITION, AIMS AND PRINCIPLES*

Botulinum toxin is a substance which decreases the muscle contraction by acting at the level of the neuro-muscular jonction (myorelaxing action).

Since 1975 physicians have used, botulinum toxin to correct squints in children, facial tics and uncontrollable eye lid movements.

In France, the first official licence ("AMM") dates from 1990 for certain pathologies in ophthalmology, ENT, physiotherapy and neurology.

In aesthetic medicine, Doctor CARRUTHERS, a Canadian ophthalmologist, is the first to have noticed that patients treated with botulinum toxin have fewer wrinkles around the eye than others. In 1990, a more observant female patient asked him to treat the eye other in order to equalise them: the aesthete indication was born.

Botulinum toxin, under the name of "BOTOX" was authorized by the USA, Food and Drug Administration (FDA) in 2002 for its use to treat the wrinkles in between the eyebrows. (Frown lines).

In February 2003, for the first time, the French authorities responsible for the control of medicines, gave an official licence (AMM) for aesthetic purposes to botulinum toxin, under the name of VISTABEL (Allergan laboratory). This licence is for the use of botulinum toxin in the treatment of glabella wrinkles (frown lines) and around the outer eye (crows feet)by a trained & competent physician and respecting certain conditions.

When botulinum toxin injections are used outside theses anatomical area, they would be used "outside AMM".

In practice, the more common indications for botulinum toxin aesthetical injections are the wrinkles between the eyebrows, (frown lines) forehead lines and crows-feet.

The principle of botulinum toxin consists of using its properties of causing muscle relaxation.

The main objective is to diminish muscle action at the level of the forehead and the eyebrows in order to decrease either the horizontal and or the vertical wrinkles caused by muscle contraction.

This will smooth the skin contours and so achieve a rejuvenating effect by diminishing muscle tension.
It should be noted that the brow position is fixed by the balance of two opposing forces, one corresponding to lowering muscles (located around the eyebrow) and the other one corresponding to the elevating muscle (the frontalis muscle). Horizontal wrinkles are due to the contraction of the frontalis muscle, and vertical ones are due to the contraction of the lowering muscles.
The main goal of this treatment is to improve wrinkles and fine lines when in a relaxed state and not to avoid muscle contraction.
Therefore results should be judged be the wrinkles seen on a peace full face.
The object of the treatment is to obtain a balance between the lowering and elevating muscles by using botulinum toxin to reduce the action of one muscle group, decrease the wrinkles related to these muscles and at the same time free the action of the opposing muscles.

The aim is to treat the muscular balance, in order to obtain facial harmony.

Treatment with botulinum toxin should be planned and managed over a period of time It is preferable at the first session, to treat progressively and to avoid the risk of "doing too much".

It is better to obtain a moderate result from the first session rather than a too severe one, it is not wise to try and obtain the maximum results possible from the first session of injections. For some people it can be necessary modify doses for several sessions before finding the optimum treatment for the individual person.

BEFORE THE INJECTIONS

To minimize the risk of bleeding in the areas of the injections it is very important, to avoid taking aspirin for 15 days before and after the session.

There is no need for any special preparation.
On the day of injection you don't need to be fasting.
It is recommended to come without any make-up or to remove it just before the injection.

Contra-indications: to Treatment with botulinum toxin

• Certain neuromuscular diseases, such as myasthenia

• Pregnancy and breast feeding: even if the pregnancy is only few days old, you must reschedule the injections after your pregnancy and breast feeding,. In case of doubt it is advisable to take a test and inform your physician.

• Known hyper sensibility to botulinum neurotoxin A or to serum-albumin

• Treatment with antibiotics from the amino-side group (particularly Amiklin, Gentamycin)

• **There are also a certain number of precautions** :

. If you are treated, with botulinum toxin injections, for pathological spasms, if you had an episode of facial paralysis, if you suffer of neuromuscular disease or blood clotting difficulties (treatment with anticoagulants) you must tell your physician who plans to do your aesthetic botulinum toxin injections. He will judge himself, after contacting your GP, if it is advisable or not to perform these injections and how to do it.

• If before injections, you take medicine, like anti-coagulating drugs or aspirin or antibiotics or if you have any health problems (infections, flu, dental abscess ...) you must imperatively tell your physician before the injections.

• Do not hesitate to tell your physician even minor health problems, in order to judge if the injections are advisable.

• You must ask all the questions that you have and mention all the treatments, you have had or are still having.

TYPE OF ANESTHESIA

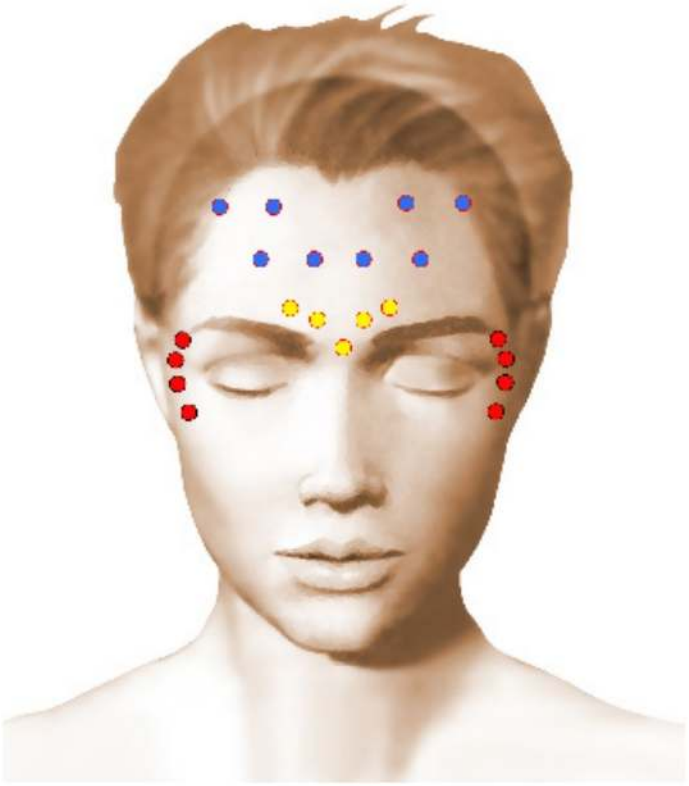
No anaesthesia is needed.

INJECTIONS PERFORMANCE

The tratment is done in the doctor's office or in an hospital, depending on your dostor's choice and habits.

This treatment consists on a serie of facial injections. The needle is fine and the injections are usually no very painful.

The time treatment is a few minutes.



AFTER THE TREATMENT : THE FOLLOW-UP

During the two hours following the injections, it is advisable not to do intensive sports and not to lie down. It is also advisable to avoid facial manipulation or massage for 24 hours following the session.
It is very important to minimize the risks of bruises or bleeding at the treated area, for 15 days before and after injections, in order to avoid injected substance leaking into muscles around the area which could produce undesirable side effects.

However, during the three days following injections, it is advised to strongly contract the injected muscles, three times a day, for about 5 seconds per muscle.
Usually, there are few signs after injection. Some slightly swollen marks may stay for 20 to 30 minutes before disappearing.
The patients can go back to their normal life after the injections.
Some rare undesirables but transitory effects may occur like:

• Redness at the injected points, rarely persisting more than 3 to 6 days.

• Ecchymosis (bruises), rarely observed and may stay a couple of days.

• Oedema : a swelling, more often around the eyes, may appear progressively within 4 to 5 days and then decrease within a few days or weeks.

• Sensibility failure : an impression of tension or rigidity of the forhead, mouth or neck , depending on the treated area, as well as a modified sensibility, related to the feeling of a "cardboard" skin, may stay for a several days.

• Fleeting ocular or facial pains : such pains have very exceptionally been described in the treated region.

However, if you have any worry in the post injection period, don't hesitate to contact your physician.

THE RESULT

The expected results consists of diminished wrinkles while limited movement continues.
It is obtained within 3 to 15 days following the injections.

Effects : you can see the result after a few days, but for about 15 days, the effects on the face may be variable (even sometimes possibly asymetrical) before stabilizing.

The result obtained after the first session stays 3 to 6 months averagely, after which the injection can be renewed.

Object of these injections is to enable an improvement but not to obtain perfection.
If the objectives of the person are realistic then results are very satisfying.
Interval between sessions of Injections : Injections have to be done several times, at intervals of 3 to 6 months, before obtaining a stable result.
After the second session, results may be more durable (6 to 8 months).
Injections may then be repeated every 3 to 6 months.

But we recommend never repeating injections at an interval of less than 3 months to avoid creating resistance to the substance, due to "a vaccination like effect".
The results can be stabilized after 3 sessions but, in certain cases, 8 to 10 sessions may be needed to get a relatively constant result.
On the contrary, if injections are stopped the muscle will return to its former function.

IMPERFECT RESULT

Localized imperfections

In a few cases, some localized imperfections (persistence of small wrinkles) may be seen which are not "real complications" are. They depend on the previous aspect of the skin, which may have been already marked with deep indelible "tissue fracture" due to the age of the wrinkle.

There may exist insufficient or even asymmetrical results: they are related to the fact, we have more or less strong muscles which are often asymmetrical.

These imperfections are usually treated with a complementary botulinum toxin injection, a month after the first injections.

However it must be , we must underlined that if a localized complementary injection may be indicated to improve the result, it shouldn't be done before 15 days after the session because the balance between the different muscles takes 15 days to establish.

Residual asymetry

An asymmetry between the two sides of the face as well as more marked winkles on side than the other exists most often before the injections. The muscle responsible for wrinkles can be stronger on side than on the other. This is generally analyzed before the injections. In such a case, the injections will be adapted to be slightly differently on one side compared with the other.

Nevertheless, a residual asymmetry can persist and eventually need a complementary injection.

Aesthetical procedures aim to render the patient happier, in a realistic way. But sometimes, we cannot obtain the persons wishes and the procedure may unfortunately increase pre-existing psychological problems. The post-injection experience can extremely different from one patient to the other and this even in case of a comparable aesthetic result.

In the case of treatment with botulinum toxin, rejuvenation is obtained with the contra party of some decrease or even disappearance of certain facial expressions. This aspect of this treatment would have been evaluated with you to avoid disappointment especially if you are an actor or public figure etc.....

POSSIBLE COMPLICATIONS

The complications are very rares.

The possible complications known at present are the following:

Facial complications :

• Headache : it can appear after the first injections and disappear within a few hours to a few days.

• Drooping Eyebrow: frontal injection may produce a slight drooping of the eyebrows. This is generally due to an original low position of the eyebrows. It will usually regress within a few weeks.

• Drooping eyelids: the injection of the glabella region may induce a partial drooping of the upper eyelid which can stay for 4 to 8 weeks. This is rare (less than 1% of the cases) and always disappears within a few weeks.

• Discomfort when smiling and swallowing: injection in the lips may induce a discomfort when smiling or small abnormal movements. Injections in the neck may produce swallowing difficulties.

• Eye dryness : due to a decrease in the secretion of tear's, which can produce keratitis, especially in patients with contact lenses (these patients should be careful to hydrate their cornea).

• Paradoxical muscle contraction and mimic disturbance: in the days following injection, the muscles may present some paradoxical movements (spontaneous contraction) these are of no lasting importance.

General complications :

They are absoluteley exceptional.

- Allergic reaction: cutaneous rash, urticaria, general allergic reaction
- Nausea, vertigo
- Tiredness, fever, flu syndrom
- Skin and mouth dryness

As well as these risks should be added the unpredicability of the durability of the results and finally any exceptional
Or unknown risk which are present for any medical procedure.

All things considered, the risks must not be overestimated,
But be aware that any injection in the face carries with it a small part of uncertainties.
The choice of a qualified physician is an assurance that he or she has the training and competence to minimize the risk of complications or manage them as well as possible if necessary.

These are the facts which we wish to bring to your attention, to complement what you were told during the consultation.

Our advice is for you to keep this document and to read it and think it over carefully after your consultation.

Once you have done this you will perhaps have further queries, or require additional information.

We are at your disposal should you wish to ask questions during your next consultation, or by telephone, or even on the day of the treatment.

PERSONNAL OBSERVATIONS :