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NEUROMODULATOR: BOTOX®, DYSPORT®, XEOMIN® (BOTULINUM A TOXIN) INFORMED CONSENT

Background

Botulinum Toxin A (Botox®, Dysport®, Xeomin®) is a neurotoxin produced by the bacterium *Clostridium botulinum* type A. Botox®, Dysport®, Xeomin® is processed and purified to produce a sterile product suitable for specific therapeutic uses. Botox®, Dysport®, Xeomin® can relax the muscles on the areas of the face which cause wrinkles associated with facial expressions. Treatment with Botox®, Dysport®, Xeomin® can cause a person's facial expression lines or wrinkles to essentially disappear. Injection of Botox®, Dysport®, Xeomin® into the small muscles between the brows causes those specific muscles to halt their function (be paralyzed), thereby improving the appearance of the wrinkles. This paralysis is temporary, and re-injection is necessary in three to four months. Botox®, Dysport®, Xeomin® injection has been FDA approved for use only in the cosmetic treatment for glabellar frown lines (the wrinkles between the eyebrows). However, other areas routinely treated are crow's feet (lateral to the eyes) and forehead wrinkles.

Botox®, Dysport®, Xeomin® is diluted to a very controlled solution and when injected into the muscles with a very fine needle, it is almost painless. Patients may feel a slight burning sensation while the solution is being injected. The procedure takes about 15 - 20 minutes. The results appear in two to ten days and lasts for three to six months, but can be shorter or longer. Within the first two days, patients may observe asymmetry or unevenness in treated areas; this usually corrects itself as the toxin takes effect. With replacement treatments, the results may tend to last longer. In a very small number of individuals, the injection does not work as satisfactorily or as long as usual and some individuals do not respond at all.

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

Risks and Complications

This list is not meant to be inclusive of all possible risks and complications associated with Botox®, Dysport®, Xeomin® as there are both known and unknown side effects associated with any medication or procedure. The possible side effects of Botox®, Dysport®, Xeomin® include but are not limited to:

1. Swelling and allergic reaction.
2. Infections can occur which in most cases are easily treatable but in rare cases a permanent scarring in the area can occur.
3. Most people have lightly swollen pinkish bumps where the injections went in, for a couple of hours or even several days.
4. Although many people with chronic headaches or migraines often get relief from Botox®, Dysport®, Xeomin®, a small percent of patients get transient headaches following treatment with Botox®, Dysport®, Xeomin®, for the first day. In a very small percentage of patients these headaches can persist for several days or weeks. Headaches may be relieved by Tylenol.
5. Local numbness, rash, pain at the injection site, flu-like symptoms with mild fever, back pain.
6. Respiratory problems such as bronchitis or sinusitis, nausea, dizziness, and tightness or irritation of the skin.
7. Bruising is possible anytime a needle is injected into the skin. This bruising can last for several hours, days, weeks, months and in rare cases the effect of bruising could be permanent.
8. While local weakness of the injected muscles is representative of the expected pharmacological action of Botox®, Dysport®, Xeomin®, weakness of adjacent muscles may occur as a result of the spread of the toxin.
9. Minor droop of eyelid(s) in approximately 2 % of injections. This is temporary and usually lasts 2-3 weeks.
10. Rarely temporary weakened tear duct function.
11. Another risk when injecting Botox®, Dysport®, Xeomin® around the eyes includes corneal exposure because people may not be able to blink the eyelids as often as they should to protect the eye. This inability to protect the eye has been associated with damage to the eye as impaired vision, or double vision, which is usually temporary. This reduced blinking has been associated with corneal ulcerations. There are medications that can help lift the eyelid, however, if the drooping is too great the eye drops are not that effective. These side effects can last for several weeks or longer. This occurs in 2 - 5 % of patients.

Alternatives

Botox®, Dysport®, Xeomin® is best used in treatment of dynamic lines, those caused by facial muscle activity. Alternative treatments for wrinkles include topical creams, chemical peels, laser treatments, surgical removal of frown muscles, forehead / brow lift, facelift, and fillers such as collagen or hyaluronic acid.

Photographs

Clinical photographs and their use for shall be used for the patient's medical record and for scientific purposes both in publications and in presentations. The patient's identity will always be protected.

Contraindications

Botox®, Dysport®, Xeomin® should not be administered to a pregnant or nursing woman.

Botox®, Dysport®, Xeomin® should not be administered to anyone with a significant neurological disease including but not limited to Myasthenia Gravis, Lambert-Eaton syndrome, Amyotrophic Lateral Sclerosis (AML, Lou Gehrig's disease), or Parkinson's disease.

Botox®, Dysport®, Xeomin® should not be administered to anyone with a known allergy to the toxin ingredients or to human albumin.

Results

The number of units injected is an estimate of the amount of Botox®, Dysport®, Xeomin® required to paralyze the muscles. There is no guarantee of results of any treatment and more than one injection may be needed to achieve a satisfactory result. Follow up is recommended two to four weeks after treatment.

Payment

Payment is due at the time of treatment. All services rendered are charged directly to the patient and the patient is personally responsible for payment. In the event of non-payment, the patient will bear the cost of collection, and/or court cost and reasonable legal fees, should this be required. Touch-ups may be required and payment is required for touch-ups. The regular charge applies to all subsequent treatments. Prices are subject to change without notice. No refunds will be given for treatments received.

Consent

By signing below, I acknowledge that I have read the foregoing informed consent, I understand it, and I agree to the treatment with its associated risks and complications. The procedure has been explained to me and my questions have been answered satisfactorily. I understand that this is an elective procedure. I understand that I will be injected with Botox®, Dysport®, Xeomin® in the area of the glabella muscles, forehead, or crow's feet area to paralyze these muscles temporarily with the goal of temporarily decreasing the wrinkles in the area(s). I understand that the number of units injected is an estimate of the amount of Botox®, Dysport®, Xeomin® required to paralyze the muscle(s) and that there is no guarantee of results of any treatment. I acknowledge that I am not pregnant or possibly pregnant, lactating or nursing, have no significant neurological disease, and have no known allergies to the toxin ingredients or to human albumin. I certify that if I have any change in my medical history I will notify my doctor immediately. I authorize clinical photographs to be taken for my medical record and for scientific purposes both in publications and presentations and that my identity will be protected. I understand that I will not be entitled to any payment as a result of these photographs. I will follow all aftercare instructions as it is crucial I do so for healing. I hereby voluntarily consent to the current and subsequent Botox®, Dysport®, Xeomin® treatments with the above understood. I hereby release Alex Eshaghian, the person injecting the Botox®, Dysport®, Xeomin®, and Alex Eshaghian Medical Corporation from liability associated with this procedure.

Patient Name (print)

Patient Signature

Date

faWitness Name (print)

Witness Signature

Date