

Neuromodulator patient consent form

What are neuromodulator's?

Dysport™ is a brand name for botulinum toxin type A, a neuromodulator that blocks the activity of muscles by temporarily inactivating the nerves that control them.

How do neuromodulator's differ?

The potency of biological activity of neuromodulator's is defined by units and is different for Dysport™ and Botox™. Hence Dysport™ and Botox™ are not interchangeable, as indicated by their unique generic names of AbobotulinumtoxinA and OnabotulinumtoxinA, respectively.

When will I see results and how long will they last?

Neuromodulator's typically start working within 24 to 48 hours and last 3 to 4 months, although individual results may vary. There may be alternative treatments to neuromodulator's, including surgery.

Neuromodulator's may cause serious side effects that can be life-threatening.

There is a possibility that the neuromodulator may spread from the injection site and elicit potentially life-threatening complications such as unexplained sudden loss of strength or muscle weakness, hoarseness or difficulty in talking and saying words clearly, loss of bladder control, difficulty in breathing or swallowing, double vision, blurred vision, and a drooping eyelids. Such adverse events have been reported as early as several hours and as late as several weeks after treatment. Seek immediate medical attention if you develop any of these symptoms. Serious side effects related to the distant spread of neuromodulator's have not been confirmed among people who have used neuromodulator's for cosmetic purposes.

What are the possible side effects of neuromodulators?

Unwanted side effects of neuromodulators include, but are not limited to, injection site discomfort or pain, local bleeding, bruising, facial asymmetry, paralysis of a nearby muscle leading to droopy eyelid, double vision, inability to close the eye, infection, dry mouth, headache, or muscle pain.

Do not use neuromodulators if you:

- are pregnant or nursing
- have an infection where neuromodulator is to be injected
- are taking aminoglycosides or anticholinergic medications
- are taking blood thinning agents such as aspirin, ibuprofen, clopidrogel bisulfate, Plavix or warfarin

- have a neuromuscular disorder such as Eaton – Lambert syndrome, Lou Gehrig’s disease, or myasthenia gravis
- have a known sensitivity to any product component including allergy to cows milk (Dysport™).

Neuromodulators contain human albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, human albumin carries an extremely remote risk for transmission of viral diseases.

ADVERSE REACTIONS:

- In clinical studies, the most frequently reported adverse events (less than or equal to 2%) were nasopharyngitis, headache, injection site pain, injection site reaction, upper respiratory tract infection, eyelid edema, eyelid ptosis, sinusitis and nausea.

Tell your doctor about all medications, vitamins, and supplements you take, especially if you have recently received an antibiotic by injection, take muscle relaxants, take allergy or cold medicine, or take a sleep medicine.

Following treatment with neuromodulator:

- avoid massage to the treated area for 3 to 4 hours
- maintain an upright position (sitting, standing, or walking) for 3 to 4 hours
- use the muscles injected by making facial expressions (frowning, puckering of the lips, etc.) for one hour
- avoid heavy lifting or aerobic exercise for 24 hours

Dysport™ is the neuromodulator you will be receiving.

I understand the above and have had the risks, benefits, and alternatives explained to me. I give my informed consent for neuromodulator injections today.

Patient Signature

Date

Print Name

Date

Witness Signature

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