Botulinum Toxin Type A Injection for Treatment of Chronic Headaches, Dystonia, Spasticity, or Other Painful Syndromes

Dystonia, and other similar syndromes, are neurologic disorders manifested by involuntary, sustained contractions (spasms) of muscles producing abnormal postures. Injections of botulinum toxin type A (Botox), a protein that causes temporary weakness of the injected muscles, may provide effective relief for dystonia, hemifacial spasm (involuntary twitching of one side of the face), spasticity, headaches, and other painful conditions due to involuntary muscle contractions. Studies involving many patients have demonstrated the safety and effectiveness of this form of treatment.

Botulinum toxin type A has been approved by the FDA for treatment of chronic headaches, blepharospasm and hemifacial spasm, cervical dystonia, and pain related to cervical dystonia but not for spasticity or other muscle pain. However, the American Academy of Neurology has deemed this drug safe and effective in the treatment of oromandibular, cervical, spasmodic, and focal dystonia. In addition, the National Institutes of Health has also issued a consensus statement that this drug is effective and safe in treating these disorders.

In addition to dystonia, recent clinical reports in the medical literature indicate that botulinum toxin type A treatments are safe and effective in the treatment of muscle spasticity (involuntary spasms often seen after spinal cord injury, head injury, and other neurologic disorders). Patients that have had head injuries and strokes often have symptoms with elements of both spasticity and dystonia.

Alternatives to botulinum toxin type A therapy include medications taken by mouth such as diazepam, benztropine, clonazepam, baclofen, and others. Additionally, certain physical therapies may be beneficial in the disorder as well.

The procedure will consist of the following: You will receive the botulinum toxin type A by injection into the muscle through the skin. The skin will be cleaned with an alcohol pad. You will usually receive three needle sticks to each muscle for even distribution of the drug and approximately 0.3 cc of fluid (less than a teaspoon) will be injected with each needle insertion.

Botulinum toxin type A may relieve symptoms for three to six months. You may notice some improvement within the next 72 hours but may not notice anything for up to two weeks. If at any time you are uncomfortable during the procedure, please let us know.

Potential benefits of this treatment would include reduction of frequency and severity of headaches, reduction in painful spasms, increased ability to range a joint such as the ankle, knee, or arm, potential to increase the speed of walking and other functional abilities, and potential for certain physical therapies to be performed more easily, such as splinting and casting.

There are risks involved in botulinum toxin type A injections. Common side effects include muscle weakness that may affect function of the limb treated, local bruising, and discomfort at the injection site. There are other conditions listed below in which these injections are performed. The common side effects related to the following disorders and their treatment include:

<table>
<thead>
<tr>
<th>For treatment of headache:</th>
<th>For treatment of Blepharospasm (involuntary eye closing):</th>
<th>For treatment of Oromandibular dystonia:</th>
<th>For treatment of Cervical dystonia:</th>
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<tbody>
<tr>
<td>Ptosis (eyelid drooping)</td>
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<td>Dysphasia (swallowing and chewing difficulties)</td>
<td>Dysphasia</td>
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<tr>
<td>Neck Pain</td>
<td>Diplopia (double vision)</td>
<td>Dysarthria (talking difficulty)</td>
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<td>Focal headache</td>
<td>Burning and Pain</td>
<td>Hoarseness</td>
<td>Singing difficulty</td>
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<td></td>
<td>Eyelid swelling and bruising</td>
<td>Drooling</td>
<td>Neck weakness</td>
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Rare side effects have been reported but are not necessarily a result of the botulinum toxin.

These include: Nausea, Fever, Difficulty breathing
Muscle soreness, Chills, Diarrhea
Headaches, Hypertension, Abdominal Pain
Light-headedness, Weakness

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**Special Warning of Risk to Females of Childbearing Potential**

The effects of botulinum toxin type A on human babies are unknown, but could cause harm.

For this reason it is necessary to:

- Use adequate birth control to avoid getting pregnant while receiving treatment.
  Inform us immediately if you get pregnant.
- This treatment may cause an allergic reaction. Potentially, this reaction could be severe and life threatening.
- As is true of all medications in medical treatment, there is always the possibility of a new or unexpected risk.

For the reasons stated above, if you have any worrisome symptoms please notify us immediately.
Our telephone number is (850) 494-0000.

By signing this consent form, I (__________________________________________) acknowledge that I have read and understand this information and that Dr. _______________________________________ has explained the potential risks and benefits of this procedure to me. Additionally, there has been adequate time allowed for me to ask questions, which have been answered to my satisfaction.

Signature of Patient

__________________________________________  Date ____________

Signature of Witness

__________________________________________  Date ____________