

INFORMED CONSENT

Dear Sir / Madam,

You have been informed about the disease/problem from which you are suffering, and for which you have been recommended treatment with botulinum toxin A or B. In addition to oral instruction by a physician the following text provides you with further information and serves as well as informed consent to botulinum toxin therapy.

Botulinum toxin is natural bacterial toxin produced by the bacterium *Clostridium Botulinum*. In this natural form it is considered one of the most toxic substances. However, the botulinum toxin used for therapeutic purposes is produced by biotechnological methods and has got only the basic structure in common with the original "wild toxin". This is thanks to the substances which allow its storage, dilution and application. In the form of the modern drug the usage of botulinum toxin is safe and can by no means endanger the patient's life. Botulinum toxin is one of the most studied drugs in the world and currently there is a huge number of clinical studies and treated patients. The physician who will administer botulinum toxin to you has had many years' experience in variety of indications, and he agreed with you on this therapy which is in his opinion indicated. Botulinum toxin is usually applied from the age of two in children and its administration is not limited by age. It is not applied to pregnant women and not recommended to those who are breast-feeding.

The onset of botulinum toxin's effect after intramuscular or subcutaneous injection is due approximately seven days after administration (the range is commonly from three to ten days, owing to the each patient's individual circumstances). Thus no immediate outcome is expected. But once the therapeutic effect of botulinum toxin is fully developed, it should last depending on the severity and nature of your illness about three months. There are considerable interpersonal differences in the botulinum toxin effect's duration. The effect may last substantially longer or shorter. The peak effect of this drug - the date when the medication is fully and maximally efficient is one month after application. Please record conscientiously the date of the effect's onset and its duration - your physician will be very interested. Furthermore, your physician will also be interested in the strength of the botulinum toxin's effect and the relevance of this therapy for you.

Besides the main positive effect of the botulinum toxin a number of so-called side effects (adverse events) might occur which are mostly transient and often take less time than the desired main effect. We do not expect them in your case but it is important to keep in mind the possibility of their occurrence. These side effects may include:

In the case of **application into the face** (cosmetic application due to wrinkles, blepharospasm, facial hemispasmus, migraine - headaches, strabismus therapy - squint and other similar applications):

- a) drooping of the eyelid (ptosis) or the inability to completely close the eye, facial paresis

- b) diplopia
- c) drooping of the mouth corner, weakness of facial muscles
- d) failure of speech intelligibility, weakened speech muscles
- e) atrophy or muscular pain at the injection site
- f) conjunctivitis or other eye inflammation (particularly if the drug is applied close to the eye)
- g) increased lacrimation or conversely dry eyes, oedema (swelling) of the lower lid (especially in case of application very close to the eye)

In the case of **application into the neck area** (in cervical dystonia, myoclonus, tic disorders, essential tremor, laryngeal dystonia, and so on)

- a) dysphagia, difficulty swallowing especially the tough food and liquids
- b) dysphonia, a voice disorder, usually hoarseness
- c) dysarthria, speech disorder, clumsiness of speech
- d) weakness of nuchal muscles manifested in the difficulty in holding the head upright
- e) dyspnoea, worsened breathing, the sense of feeling that you cannot “fully breathe” highlighted tremor of the head (especially in cervical dystonia and essential tremor)
- g) pain in application site

In the case of **application into the limbs** (especially in children with cerebral palsy, in patients after stroke and intracerebral hematoma, with essential tremor, with graphospasm and so on)

- a) weakening of the muscle groups greater than desired, temporary loss of already acquired skills
- b) weakening of the limb which leads to transient functional failure of movement
- c) deterioration in gait (i.e. the opposite effect to that we want to do with botulinum toxin)
- d) micturition disorders, usually with injection very high into the thigh

There are **other areas** where the botulinum toxin may be administered - for example the underarm in the case of axillary hyperhidrosis. In the case of migraine - besides the face and scalp surface - also into the neck muscles and shoulders. For treatment of hyperhidrosis with botulinum toxin there may paradoxically occur an increase in sweating as a side effect. Adverse events in the neck and limb application are mentioned above. Another area of administration of botulinum toxin is a dysfunctional bladder - as a side effect there can be a urinary tract infection.

Besides the side effects of botulinum toxin listed above there can rarely occur **the general adverse effects** of intramuscular, subcutaneous or otherwise administered injections.

- a) hematoma (blood bruising, welt) at the injection site

- b) pain in the injection site either during injection or after injection and longer lasting
- c) overall fatigue and inability to perform, weariness (especially children can react in this way)
- d) fever (particularly among children)
- e) muscle atrophy in the application site
- f) muscle weakness
- g) infection, cold (especially in children)

The side effects listed above may also occur in other areas than the one where applied but they are extremely rare.

All the side effects of botulinum toxin usually appear in a minimum of patients and their gravity might vary from the very mild and almost unobtrusive to the more serious which already bother the patient. However, please tell your physician if anything wrong occurs, at the periodic appointment or sooner if necessary.

Please inform your physician:

- If you suffer from increased bleeding or you have been taking drugs that affect blood coagulation (blood precipitation) - this is crucial information
- If you suffer from an infectious or contagious disease - it is also vital information.

Botulinum toxin must not be applied if you have on-going infection such as the common cold, angina, influenza, etc. For a physician it is also very important to know all the medications you have been taking and any disease you suffer from or you are being treated for. It is also essential to inform the physician of any allergies you have. Please inform your physician of such facts before application.

I confirm with my signature that I have been informed by Eduard Minks, MD, PhD, about the nature of my disease/problem and about the treatment with single and repeated applications of botulinum toxin A or B. I was also informed about the possible adverse effects/side effects of botulinum toxin and I understand all the oral instructions and all the information in this form. I request and consent to botulinum toxin therapy.

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Patient's signature

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Physician's signature

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