BTXA
(BOTULINUM TOXIN TYPE A FOR INJECTION)

DESCRIPTION

BTXA (Botulinum Toxin Type A for Injection) is a sterile, lyophilized form of purified botulinum toxin type A, produced from the crude toxin of the culture of the Hall strain of Clostridium botulinum grown in a medium containing trypticase and yeast extract. A series of purifying procedure were taken to form a crystalline complex consisting of the active high molecular weight toxin protein and an associated hemagglutinin. After re-dissolved and dialyzed the crystalline toxin, an accurate amount of the sterile filtered (0.2 microns) toxin were added to a solution containing gelatin-dextran-sucrose, then lyophilized.

Each vial of BTXA contains 100 or 50 units (U) of C. botulinum toxin type A, 5 mg of gelatin, 25 mg of dextran and 25 mg of sucrose. Dilute with sterile normal saline according to different needs before using. The white loose product turns to be colorless or yellowish transparent solution after the reconstitution.

One unit (U) of BTXA corresponds to 1 LD_{50} of Botulinum Toxin Type A while being intraperitoneally injected into mouse.

BTXA could block neuromuscular conduction by inhibiting the release of acetylcholine and therefore causes local muscle flaccid paralysis.

INDICATIONS

BTXA is indicated for the treatment of blepharospasm, hemifacial spasm in adults and some types of strabismus, especially for acute paralytic strabismus, comitant strabismus, strabismus caused by endocrine myopathy and strabismus which cannot be corrected through operation.

USAGE AND DOSAGE

1. Position for injection
   1) For blepharospasm: the injection should be taken intramuscularly at several points of upper and lower lids, i.e., taking 4 to 5 points of injection into orbicularis oculi of medial and lateral or lateral canthus temporal.
   2) For hemifacial spasm: besides the points mentioned above, three other points on middle, lower face and cheek should be given intramuscularly. BTXA may be given at the points of two sides of eyebrow, upper lip or the lower jaw according to the diseases.
   3) For strabismus: the BTXA is injected using a coaxial electrode needle with electromyographic guidance or amplifier under topical anesthesia of 0.5% Decarine. The injections into extraocular muscles are selected according to the type and position of strabismus.
2. Dosage
   1) For blepharopasm and hemifacial spasm: the injection could be given following above instructions. The initial dose of each point is 2.5 U / 0.05 ml or 2.5 U / 0.1 ml. If the initial treatment is considered insufficient one week later, a supplementary injection may be given. Double dose of 5 U / 0.1 ml could be given to recrudescent patients. But the limitation of total dose of 25 U for one injection and 200 U for one month should not be exceeded.
   2) For strabismus: for vertical and horizontal muscle strabismus of less than 20 prism diopters, the initial dose into each muscle is 1.25-2.5 U; for horizontal strabismus of 20-40 prism diopters, the initial dose into each muscle is 2.5 U; for horizontal strabismus of 40-50 prism diopters, the initial dose into each muscle is 2.5 U and can be increased (to 5.0 U each time) depending on the response; for persistent VI cranial nerve paralysis lasted for more than one month, 1.25-2.5 U dose could be injected into medial rectus.

   The injecting volume into each muscle should not exceed 0.1 ml.

   To patients, having insufficient response, supplementary injection could be given. To recrudescent patients, the dose can be repeated or increased irregularly. But for each muscle the maximum dose should be less than 5 U / inj.

3. The Dilution of BTXA

The dilution of BTXA with sterile normal saline should be done carefully on the basis of real needs. Following is a reference table of dilution to be recommended:

	U / vial	
	50	100
U / 0.1 ml	The volume of diluent (ml)	
10.0	0.5	1.0
5.0	1.0	2.0
2.5	2.0	4.0
1.25	4.0	8.0

Shaking the vial gently after adding sterile normal saline to the complete dissolving.

The reconstituted BTXA should be used at once or stored in refrigerator at 2 to 8°C and to be used within 4 hours. The container and the syringe used with the drug as well as the residual BTXA solution should be disposed after sterilization.

SIDE EFFECTS

1. Temporary ptosis of the eyelid, drawback of the lower eyelid, reduced blinking, eyelid close incompletely, weakness of facial muscles, etc. may occur to a few patients who received BTXA therapy for blepharospasm and hemifacial spasm. However, all the symptoms will disappear without any therapy within 3 to 8 weeks.
2. Temporary and different degree of ptosis of the eyelid, vertical deviation and rarely mydriasis, which related to the diffusion of the toxin to the muscles adjacent, may occur to some patients who received BTXA therapy for strabismus. The symptoms will disappear without any therapy within a few weeks.

CONTRAINDICATIONS

BTXA is contraindicated in individuals with anaphylactic constitution and known hypersensitivity to this preparation.

PRECAUTIONS

1. BTXA must be kept, issued, registered by special person and administered only to the patients with above indications. Physicians administering especially during the treatment of strabismus, have to be trained prior, know extraocular and facial muscles anatomy and be good at electromyographic amplifier technique.
2. The injection procedure should be taken later to patients who have fever, acute infectious diseases and carefully to the patients with heart, liver, lung diseases, active tuberculosis, blood diseases, pregnant women.
3. Botulinum toxin may be potentiated by aminoglycoside antibiotics (such as gentamicin). This kind of drugs should not be taken during the administration of BTXA.
4. BTXA is in low effect or without any effect to the patients in the following situations: strabismus above 50 prism diopters, fixed strabismus, Duane's syndrome due to weak lateral rectus, strabismus caused by excessively corrected operation, chronic paralysis strabismus, chronic VI or III cranial nerve paralysis, serious muscle fiber contracture.
5. 1:1000 adrenaline should be prepared in case of occasional accident. Short period of observation is recommended to the patients who just received BTXA injection.

HOW SUPPLIED

100 U / Vial, 50 U / Vial

SHELF LIFE

3 years from the date of lyophilization.

STORAGE

Store at a temperature of 2 to 8°C (35 to 46°F)

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