onabotulinum toxin A (bot-lye-num tox-in)

Botox, Botox Cosmetic

Classification
Therapeutic: cosmetic agents
Pharmacologic: neurotoxins

Pregnancy Category C

Indications

Action
Produces partial chemical denervation by inhibiting the release of acetylcholine. Result is local decrease in muscle activity.

Pharmacokinetics
Absorption: Minimal systemic absorption; action is primarily local.
Distribution: Unknown.
Metabolism and Excretion: Unknown.

Contraindications/Precautions
Contraindicated in: Hypersensitivity; Presence of infection at planned injection sites; Acute urinary tract infection and/or acute urinary retention (for urinary incontinence indication); OB: Potential for spontaneous abortion or fetal deformity.

Use Cautiously in: Peripheral motor neuropathic diseases (e.g. amyotrophic lateral sclerosis, motor neuropathy) or neuromuscular junctional disorders (e.g. myasthenia gravis, Lambert—Eaton syndrome) (risk of significant systemic effects such as dysphagia or respiratory compromise); Inflammation at planned injection site; Marked facial asymmetry, ptosis, excessive dermatochalasis, thick sebaceous skin, inability to lessen glabellar lines by physical spreading; Excessive weakness or atrophy in target muscles; Swallowing or breathing problems (for treatment of cervical dystonia; risk of dysphagia); Respiratory problems (for treatment of spasticity; risk of pulmonary infection and worsening condition).

Lactation: Lactation; Pedi: Children <12 yr (safety not established); Geri: Use lowest effective dose.

Adverse Reactions/Side Effects

Special Monitoring
None

Interactions
None

Route ONSET PEAK DURATION
IM† 1–2 days unknown 3–4 mo
IM‡ 1–2 days unknown 3–4 mo
IM* 2 wk unknown 3–4 mo
IM†† unknown unknown 3–4 mo
IM** 1–2 days unknown 2–6 wk
IM^ unknown unknown 200 days
IM^^ unknown unknown 3 mo

† Cosmetic; ‡ Blepharospasm; * Cervical dystonia; †† Spasticity; ** Strabismus; ^ Axillary hyperhidrosis; ^^ Migraines.

Metabolism and Excretion: Unknown.
Half-life: Unknown.
TIME/ACTION PROFILE (improvement)

Botox, Botox Cosmetic

Metabolism and Excretion: Unknown.
Half-life: Unknown.
TIME/ACTION PROFILE (improvement)

ROUTE ONSET PEAK DURATION
IM† 1–2 days unknown 3–4 mo
IM‡ 1–2 days unknown 3–4 mo
IM* 2 wk unknown 3–4 mo
IM†† unknown unknown 3–4 mo
IM** 1–2 days unknown 2–6 wk
IM^ unknown unknown 200 days
IM^^ unknown unknown 3 mo

† Cosmetic; ‡ Blepharospasm; * Cervical dystonia; †† Spasticity; ** Strabismus; ^ Axillary hyperhidrosis; ^^ Migraines.
Interactions
Drug-Drug: Neuromuscular effects may be potentiated by aminoglycosides, quinidine, and other drugs that alter neuromuscular transmission. Additive effects may occur with other forms of botulinum toxin.

Route/Dosage
Reduction of Glabellar Lines
IM (Adults): 0.1 mL (4 units) into each of five sites (two in each corrugator muscle and one in the procerus muscle; total dose of 20 units); not more frequently than every 3 mo.

Reduction of Lateral Canthal Lines
IM (Adults): 0.1 mL (4 units) into each of three sites per side in the lateral orbitetomas such muscle (12 units per side); total dose of 20 units; not more frequently than every 3 mo.

Upper Limb Spasticity
IM (Adults): Biceps brachii—100–200 units divided in 4 sites; not more frequently than every 3 mo; Flexor carpi radialis or flexor carpi ulnaris—12.5–50 units in 1 site; not more frequently than every 3 mo; Flexor digitorum profundus or flexor digitorum sublimis—30–50 units in 1 site; not more frequently than every 3 mo.

Cervical Dystonia
IM (Adults): Mean dose is 236 units divided among the affected muscles in patients previously treated with botulinum toxin; initial dose should be lower in previously untreated patients; subsequent dosing should be based on patient's head and neck position, localization of pain, muscle hypertrophy, patient response and previous tolerability; total dose injected into sternocleidomastoid muscles should be 100 units (to minimize incidence of dysphagia); not more frequently than every 3 mo.

Auxiliary Hyperhidrosis
IM (Adults): 50 units per axilla; may repeat when clinical effect diminishes.

Blepharospasm
IM (Adults and Children): 1.25–2.5 units into the medial and lateral pretarsal orbitetomas of the upper lid and into the lateral pretarsal pretarcalis oculi of the lower lid; not more frequently than every 3 mo.

Strabismus
IM (Adults and Children): Vertical muscles and for horizontal strabismus: 20-50 units divided—2.5–2.5 units in any one muscle, horizontal strabismus of 20–50 prism diopters—2.5–5 units in any one muscle. Persistent IF nerve palsy of 1 or 2 mm—1–2.5–2.5 units in the medial rectus muscle.

Chronic Migraine
IM (Adults): 155 units divided among 7 specific head/neck muscle areas (see prescribing information for dose to be injected into each area) every 12 wk.

Urinary Incontinence
IM (Adults): 200 units injected into the detrusor muscle every 12 wk.

Overactive Bladder
IM (Adults): 100 units injected into the detrusor muscle every 12 wk.

NURSING IMPLICATIONS
Assessment
- Assess for signs of anaphylactic reaction (dyspnea, rash, pruritus, laryngeal edema, wheezing) following administration. Keep epinephrine, an antihistamine, and resuscitation equipment close by in the event of an anaphylactic reaction.
- Monitor for asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. Medication may spread from the injection site to distant parts of the body.

Implementation
- Physicians administering botulinum toxin should understand neuromuscular anatomy of the area involved and potential alterations.
- Botulinum toxin products are not interchangeable. Determine appropriate product prior to administration.
- Injections should be made no more frequently than every 3 mo and using the lowest effective dose.
- Botox Cosmetic: Reconstitute vial with 2.5 mL of 0.9% NaCl without preservatives for a concentration of 4.0 units/mL. Inject treatment dose of 20 units in 0.5 mL. Inject diluent directly into vial at a 45° angle. Discard if diluent does not pull diluent into vial. Rotate vial gently and record date and time of reconstitution.
onabotulinum toxin A

on label. Solution should be clear, colorless, and free of particulate matter. Reconstitute solution and use within 4 hr of reconstitution; do not freeze. Discard unused solution 1 dose/box reconstituted should be stored in refrigerator.

\[ \text{IM:} \]

- Draw at least 0.5 mL of reconstituted solution into tuberculin syringe and expel any air bubbles from syringe barrel. Remove needle used for reconstitution and replace with a 30-gauge needle, ensure patency of needle before injection. Solution should be stored in refrigerator.

- Botox: Reconstitute with 2.5 mL of 0.9% NaCl without preservatives. Draw up maximum amount of solution in appropriate size syringe (see Package insert). Discard reconstituted solution if vacuum does not pull diluent into vial. Rotate vial gently and record date and time of reconstitution on label. Solution should be clear, colorless, and free of particulate matter. Refrigerate solution and use within 24 hr of reconstitution; do not freeze. Discard unused solution. Unopened vials should be stored in refrigerator.

- IM: Follow specific dose and administration recommendations for each indication.

Patient/Family Teaching

- Review Medication Guide with patient prior to each administration.

- Inform patient that the material has the potential to spread from the injection site to distant parts of the body. May occur within hrs or several weeks after injection. Advise patient to notify health care professional immediately if swallowing, speech, or respiratory disorders arise.

- Advise female patient to notify health care professional if pregnancy is planned or suspected or breast feeding.

Evaluation/Desired Outcomes

- Decreased brow furrow and lateral canthal lines beginning 1–2 days after injection and increasing in intensity during the first week.

- Decreased muscle tone in upper limbs.

- Decreased severity of abnormal head position and neck pain.

- Decreased sweating.

- Decreased blepharospasm.

- Decreased strabismus.

- Decreased frequency and duration of headaches.

- Decreased urinary incontinence.

Why was this drug prescribed for your patient?