Dysport (abobotulinumtoxinA) - Drug Summary

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Dysport
(abobotulinumtoxinA)

BOXED WARNING

Distant spread of toxin effects (eg, asthenia, generalized muscle weakness, diplopia) reported hrs to weeks after inj. Swallowing and breathing difficulties can be life threatening and there have been reports of death. Risk of symptoms is greatest in children treated for spasticity but can also occur in adults. In unapproved uses and approved indications, cases of spread of effect have been reported at doses comparable to or lower than the max recommended total dose.

THERAPEUTIC CLASS

Acetylcholine release inhibitor

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Cervical Dystonia

Initial: 500 U IM as a divided dose among affected muscles in patients w/ or w/o a history of prior treatment w/ botulinum toxin
Titrate: Adjustments can be made in 250 U steps according to response; total dose administered in a single treatment should be between 250 U and 1000 U
Max: 1000 U

Retreatment, if needed, should not occur in intervals of <12 weeks

Glabellar Lines

Temporary improvement in the appearance of moderate to severe glabellar lines associated w/ procerus and corrugator muscle activity

<65 Years:
Total of 50 U IM in 5 equal aliquots of 10 U each

Inject into each of 5 sites: 2 in each corrugator muscle, and 1 in the procerus muscle

Administer no more frequently than every 3 months

When used for retreatment, reconstitute and inject using the same techniques as initial treatment

Spasticity

To decrease the severity of increased muscle tone in elbow flexors, wrist flexors, and finger flexors

Dosing by Muscle:
Flexor Carpi Radialis: 100-200 U (1-2 inj)
Flexor Carpi Ulnaris: 100-200 U (1-2 inj)
Flexor Digitorum Profundus: 100-200 U (1-2 inj)
Flexor Digitorum Superficialis: 100-200 U (1-2 inj)
Brachialis: 200-400 U (1-2 inj)
Brachioradialis: 100-200 U (1-2 inj)
Biceps Brachii: 200-400 U (1-2 inj)
Pronator Teres: 100-200 U (1 inj)

Although actual location of inj sites can be determined by palpation, use of inj guiding technique (eg, electromyography, electrical stimulation) is recommended

Generally, no more than 1mL should be administered at any single inj site

Repeat treatment should be administered when the effect of a previous inj has diminished, but no sooner than 12 weeks after the previous inj

ADMINISTRATION

IM route

Supplied as a single-use vial.
Once reconstituted, store in the original container at 2-8°C (36-46°F); do not freeze. Protect from light. Use w/in 24 hrs.

Cervical Dystonia
Preparation and Administration:
Reconstitute each 500 U vial w/ 1mL of preservative-free 0.9% NaCl inj to yield a sol of 50 U/0.1mL.
Reconstitute each 300 U vial w/ 0.6 mL of preservative-free 0.9% NaCl inj to yield a sol equivalent to 50 U/0.1mL.

Glabellar Lines
Preparation and Administration:
Reconstitute each 300 U vial w/ 2.5mL of preservative-free 0.9% NaCl inj prior to inj; concentration of resulting sol will be 10 U/0.08mL (12 U/0.1mL) to be delivered in 5 equally divided aliquots of 0.08mL each.
AbobotulinumtoxinA may also be reconstituted w/ 1.5mL of preservative-free 0.9% NaCl inj for a sol of 10 U/0.05mL (20 U/0.1mL) to be delivered in 5 equally divided aliquots of 0.05mL each.
Use a 30-gauge needle when administering.

Inj Technique:
In order to reduce the complication of ptosis, the following steps should be taken:
1. Avoid inj near the levator palpebrae superioris, particularly in patients w/ larger brow depressor complexes.
2. Medial corrugator inj should be placed at least 1cm above the bony supraorbital ridge.
3. Ensure the injected volume/dose is accurate and where feasible kept to a minimum.
4. Do not inject toxin closer than 1cm above the central eyebrow.

To inject abobotulinumtoxinA, advance the needle through the skin into the underlying muscle while applying finger pressure on superior medial orbital rim.

Upper Limb Spasticity
Preparation and Administration:
The recommended concentration is 100 U/mL or 200 U/mL w/ preservative-free 0.9% NaCl inj; refer to PI for appropriate dilution instructions.

HOW SUPPLIED

Inj: 300 U, 500 U

CONTRAINDICATIONS

Allergy to cow's milk protein, infection at the proposed inj site(s).

WARNINGS/PRECAUTIONS

Not interchangeable w/ other botulinum toxin products; cannot be compared or converted into U of any other botulinum toxin products. May weaken neck muscles that serve as accessory muscles of ventilation. May require immediate medical attention if problems w/ swallowing, speech, or respiratory disorders develop. Caution w/ surgical alterations to facial anatomy, excessive weakness or atrophy in the target muscle(s), marked facial asymmetry, inflammation at the inj site(s), ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin, or the inability to substantially lessen glabellar lines by physically spreading them apart. Increased incidence of eyelid ptosis w/ higher doses. Closely monitor patients w/ peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome); may increase risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses. Contains albumin; carries remote risk of transmitting viral diseases and Creutzfeldt-Jakob disease. Caution in elderly.

ADVERSE REACTIONS

Discomfort at inj site, dry mouth, fatigue, headache, nasopharyngitis, muscular weakness, musculoskeletal pain, URTI, dysphagia, neck pain, dysphonia, eye disorders, dizziness, UTI.

DRUG INTERACTIONS

Potentiation of toxin effect may occur w/ aminoglycosides or w/ other agents interfering w/ neuromuscular transmission (eg, curare-like agents); monitor closely. Use of anticholinergic drugs after administration may potentiate systemic anticholinergic effects. Excessive weakness may be exacerbated if another botulinum toxin is administered before effects resolve from the previous botulinum toxin inj administration. Use of a muscle relaxant before/after administration may exaggerate excessive weakness.

PREGNANCY AND LACTATION

Pregnancy: Category C.
Lactation: Safety not known in nursing.

MECHANISM OF ACTION

Acetylcholine release inhibitor; inhibits release of acetylcholine from peripheral cholinergic nerve endings. Binds to specific surface receptors on nerve endings, internalizes by receptor mediated endocytosis, leading to intracellular blockage of neurotransmitter exocytosis into the neuromuscular junction.

ASSESSMENT

Assess for allergy to cow's milk protein, infection/inflammation at proposed inj site(s), preexisting swallowing/breathing difficulties, surgical facial alterations, excessive weakness or atrophy in the target muscle(s), marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin, inability to substantially lessen glabellar lines by physically spreading them apart, preexisting neuromuscular disorders, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for spread of the toxin effects, weakening of neck muscles, and swallowing/speech/respiratory disorders. Monitor patients w/ peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders.

PATIENT COUNSELING

Advise to notify physician if any unusual symptoms develop (eg, difficulty w/ swallowing, speaking, or breathing) or if any known symptom persists or worsens. Instruct to avoid driving or engaging in potentially hazardous activities if loss of strength, muscle weakness, blurred vision, or drooping eyelids occur.

STORAGE

2-8°C (36-46°F). Protect from light.

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