Clinical improvement generally occurs within 2 weeks. Patients should be considered for re-injection when the clinical effect of the previous injection has diminished (median duration in Phase 3 clinical trials was 256 - 295 days (36 - 42 weeks) for BOTOX® 200 U) but no sooner than 3 months from the prior bladder injection.

Chronic Migraine

The recommended dose for treating chronic migraine is 155 U to 195 U administered intramuscularly (i.m.) using a 30-gauge, 0.5 inch needle as 0.1 mL (5 U) injections per each site. Injections should be divided across 7 specific head/neck muscle areas as specified in Table 1 below. A 1-inch needle may be needed in the neck region for patients with extremely thick neck muscles. With the exception of the procerus muscle, which should be injected at 1 site (midline), all muscles should be injected bilaterally with the minimum dose per muscle as indicated below, with half the number of injection sites administered to the left and half to the right side of the head and neck. If there is a predominant pain location(s), additional injections to one or both sides may be administered in up to 3 specific muscle groups (occipitalis, temporalis and trapezius), up to the maximum dose per muscle as indicated in Table 1 below.

The recommended re-treatment schedule is every 12 weeks.

Table 1: BOTOX® Dosing by Muscle for Chronic Migraine

	Recommended Dose
Head/Neck Area	**Total Number of Units (U) (number of IM injection sites[a])**
Frontalis[b]	20 U (4 sites)
Corrugator[b]	10 U (2 sites)
Procerus	5 U (1 site)
Occipitalis[b]	30 U (6 sites) up to 40 U (up to 8 sites)
Temporalis[b]	40 U (8 sites) up to 50 U (up to 10 sites)
Trapezius[b]	30 U (6 sites) up to 50 U (up to 10 sites)
Cervical Paraspinal Muscle Group[b]	20 U (4 sites)
Total Dose Range:	155 U to 195 U

[a] *1 IM injection site = 0.1 mL = 5 U BOTOX®*

[b] *Dose distributed bilaterally for minimum dose*

Cervical Dystonia (spasmodic torticollis)

Dosing must be tailored to the individual patient based on the patient's head and neck position, localisation of pain, muscle hypertrophy, patient's body weight and patient response.

Multiple injection sites allow BOTOX® to have more uniform contact with the innervation areas of the dystonic muscle and are especially useful in larger muscles. The optimal number of injection sites is dependent upon the size of the muscle to be chemically denervated. The treatment of cervical dystonia typically may include, but is not limited to, injection of BOTOX® into the sternocleidomastoid, levator scapulae, scalene, splenius capitis and/or the trapezius muscle(s).

A 25-, 27- or 30-gauge needle should be used for superficial muscles and a needle of appropriate length may be used for deeper musculature. For cervical dystonia, localisation of the involved muscles with electromyographic guidance may be useful.