Myobloc® (rimabotulinumtoxinB) – New indication

- On August 20, 2019, the FDA approved US WorldMeds' Myobloc (rimabotulinumtoxinB), for the treatment of chronic sialorrhea in adults.

- Myobloc is also approved for the treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults.

- The efficacy of Myobloc was evaluated in a double-blind study in 187 adult patients with chronic, troublesome sialorrhea. Patients had chronic sialorrhea associated with Parkinson's disease, amyotrophic lateral sclerosis, stroke, and other causes. Patients were randomized to receive Myobloc 2,500 units, Myobloc 3,500 units, or placebo. The co-primary efficacy endpoints were the change from baseline in unstimulated salivary flow rate (USFR) and the Clinical Global Impression of Change (CGI-C; scores ranging from "1 = very much improved" to "7 = very much worse") assessed 4 weeks after treatment.

    — The mean USFR change from baseline (g/min) at week 4 was -0.37, -0.36, and -0.07 for Myobloc 2,500 units, Myobloc 3,500 units, and placebo, respectively ($p < 0.0001$ vs. placebo for both Myobloc dosages).
    — The CGI-C score at week 4 was 2.38, 2.45, and 3.59 for Myobloc 2,500 units, Myobloc 3,500 units, and placebo, respectively ($p < 0.0001$ vs. placebo for both Myobloc dosages).

- The efficacy of Myobloc was also in a double-blind study in 54 patients with troublesome chronic sialorrhea and Parkinson's disease. Patients were randomized to receive Myobloc 1,500 units, Myobloc 2,500 units, Myobloc 3,500 units, or placebo. The co-primary efficacy endpoints were the change from baseline in USFR and the CGI-C score assessed 4 weeks after treatment.

    — The mean USFR change from baseline (g/min) at week 4 was -0.44, -0.38, -0.30, and 0.01 for Myobloc 1,500 units, Myobloc 2,500 units, Myobloc 3,500 units, and placebo, respectively ($p < 0.0001$ vs. placebo for both Myobloc 1,500 and 2,500 units; $p < 0.001$ vs. placebo for Myobloc 3,500 units).
    — The CGI-C score at week 4 was 2.14, 2.00, 1.62, and 3.93 for Myobloc 1,500 units, Myobloc 2,500 units, Myobloc 3,500 units, and placebo, respectively ($p < 0.0001$ vs. placebo for all Myobloc dosages).

- Myobloc carries a boxed warning for distant spread of toxin effect.

- The most common adverse reactions (> 5% at any dose and > 5% more common than placebo) with Myobloc use were dry mouth and dysphagia.

- The recommended dosage of Myobloc for chronic sialorrhea is 1,500 to 3,500 units, divided among the parotid and submandibular glands.

    — The typical duration of effect of each treatment is up to 3 months; however, the effect may vary in individual patients.

Continued . . .

— The frequency of Myobloc repeat treatments should be determined by clinical response but should generally be no more frequent than every 12 weeks.
— Refer to the Myobloc drug label for dosing for treatment of cervical dystonia.

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