Dysport® (abobotulinumtoxinA) – Expanded indication

- On June 16, 2017, Ispen announced the FDA approval of Dysport (abobotulinumtoxinA) for the treatment of lower limb spasticity in adults.
    - Previously, Dysport was only approved for the treatment of lower limb spasticity in pediatric patients ≥ 2 years of age and for the treatment of upper limb spasticity in adult patients.
    - Dysport is also indicated for the treatment of adults with cervical dystonia and for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients < 65 years of age.
- Lower limb spasticity impacts a person's movement. In adults, approximately one in three stroke patients, one in three patients with spinal cord injury, one in six patients with traumatic brain injury, and two in three patients with multiple sclerosis will develop lower limb spasticity. Adults with cerebral palsy also commonly experience spasticity in their lower limbs.
- The efficacy of Dysport for the treatment of lower limb spasticity was evaluated in a placebo-controlled study of 381 adult patients treated with Dysport following a stroke or traumatic brain injury. The primary endpoint was change in the Modified Ashworth Scale (MAS), a measure of lower limb spasticity.
    - Patients treated with Dysport showed significant improvements in MAS at the ankle joint at week 4 vs. placebo (Dysport 1,500 units: -0.8 vs. -0.5, respectively; $p < 0.05$; Dysport 1,000 units: -0.6 vs. -0.5, respectively; p value not reported).
    - The duration of response for the majority of patients was between 12 to 16 weeks.
- Similar to other botulinum toxin products, Dysport carries a boxed warning for distant spread of toxin effect.
- The most common adverse reactions (≥ 5%) with Dysport use for the treatment of lower limb spasticity in adults were falls, muscular weakness, and pain in extremity.
- The dose of Dysport is selected based on muscles affected, severity of muscle spasticity, prior response, and adverse reaction history following treatment with Dysport or other botulinum toxin A products.
    - The recommended dose of Dysport for the treatment of lower limb spasticity in adults is up to 1,500 units.
    - Refer to the drug label for dosing recommendations for all other indications.