Dysport® is a proven first-line treatment option

1. Vacuum. When reconstituting Dysport®, insert the needle into the vial and allow the diluent to be pulled into the vial by partial vacuum. Do not use the vial if no vacuum is observed.

2. Swirl. Swirl Dysport® gently in the vial to dissolve, rather than shaking or rolling.

3. Vent. When using more than 2 mL of diluent, vent the vial to release the pressure if entering the vial again to withdraw the diluted Dysport®.

Reconstituted Dysport® should be a clear, colorless solution, free of particulate matter; otherwise it should not be injected.

To inject, remove the needle used to reconstitute Dysport® and attach an appropriately sized new sterile needle to administer the injection. Inject into target muscle(s) within 24 hours of reconstitution.

Dysport® should be used only for one injection session and for only one patient after reconstitution.

Once reconstituted, Dysport® should be stored in the original container, in a refrigerator at 2°C to 8°C (36°F to 46°F), protected from light for up to 24 hours. It must be discarded if not used within 24 hours. Do not freeze reconstituted Dysport®. Discard the vial and needle in accordance with local regulations.

INDICATIONS

Dysport® (abobotulinumtoxinA) for injection is indicated for the treatment of:

- Adults with cervical dystonia
- Spasticity in adult individuals
- Lower limb spasticity in pediatric patients 2 years of age and older

IMPORTANT SAFETY INFORMATION

Warning: Distant Spread of Toxin Effect

Postmarketing reports indicate that the effects of Dysport® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dyspnea, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but can also occur in adults treated for spasticity and dystonia, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including upper limb spasticity in children, and in approved indications, cases of spread of effect beyond the treated area have been reported.

Contraindications

Dysport® is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components; or in the presence of infection at the proposed injection site(s), or in patients known to be allergic to cow’s milk protein. Hypersensitivity reactions including anaphylaxis have been reported. (abobotulinumtoxinA)

Warnings and Precautions

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of Dysport® are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of Dysport® cannot be compared to or converted into units of any other botulinum toxin products assessed with any other specific assay method.

Dysphagia and Breathing Difficulties

Treatment with Dysport® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant side effects occur, additional respiratory muscles may be involved. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several weeks, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin.

Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of Dysport®.

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and manufacturing processes, it carries an extremely remote risk for transmission of vCJD and variant Creutzfeldt-Jakob disease (vCJD). There is no significant risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of CJD or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

Intradermal Immune Reaction

The possibility of an immune reaction when injected intradermally is unknown. The safety of Dysport® for the treatment of hyperhydrosis has not been established. Dysport® is approved only for intramuscular injection.

Most Common Adverse Reactions

- Adults with cervical dystonia (≥5% and greater than placebo): muscular weakness, dysphagia, dyspnea, dry mouth, injection site discomfort, fatigue, headache, dysphagia, dry mouth, injection site discomfort, fatigue, headache, dyspnea, injection site pain, eye disorders.
- Pediatric patients with lower limb spasticity (≥10% and greater than placebo): upper respiratory tract infection, nasopharyngitis, influenza, pharyngitis, cough, and pyrexia.

Drug Interactions

Co-administration of Dysport® and amnoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of botulinum toxin may be potentiated. Use of anticholinergic drugs after administration of Dysport® may potentiate systemic anticholinergic effects, such as blurred vision. The effect of administering different botulinum neurotoxins at the same time or within several months of each other is unknown. Excessive weakness may be exacerbated by another administration of botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of Dysport®.

Use in Pregnancy

Based on animal data, Dysport® may cause fetal harm. There are no adequate and well-controlled studies in pregnant women. Dysport® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pediatric Use

Based on animal data Dysport® may cause atrophy of injected and adjacent muscles, decreased bone growth, length, and mineral content, delayed sexual maturation, and decreased fertility.

Geriatric Use

In general, elderly patients should be observed to evaluate their tolerability of Dysport® due to the greater frequency of concomitant disease states. The effect of Dysport® in these patients is generally the same as that in younger adults. Elderly patients with dementia of the Alzheimer’s type are more susceptible to these complications.

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