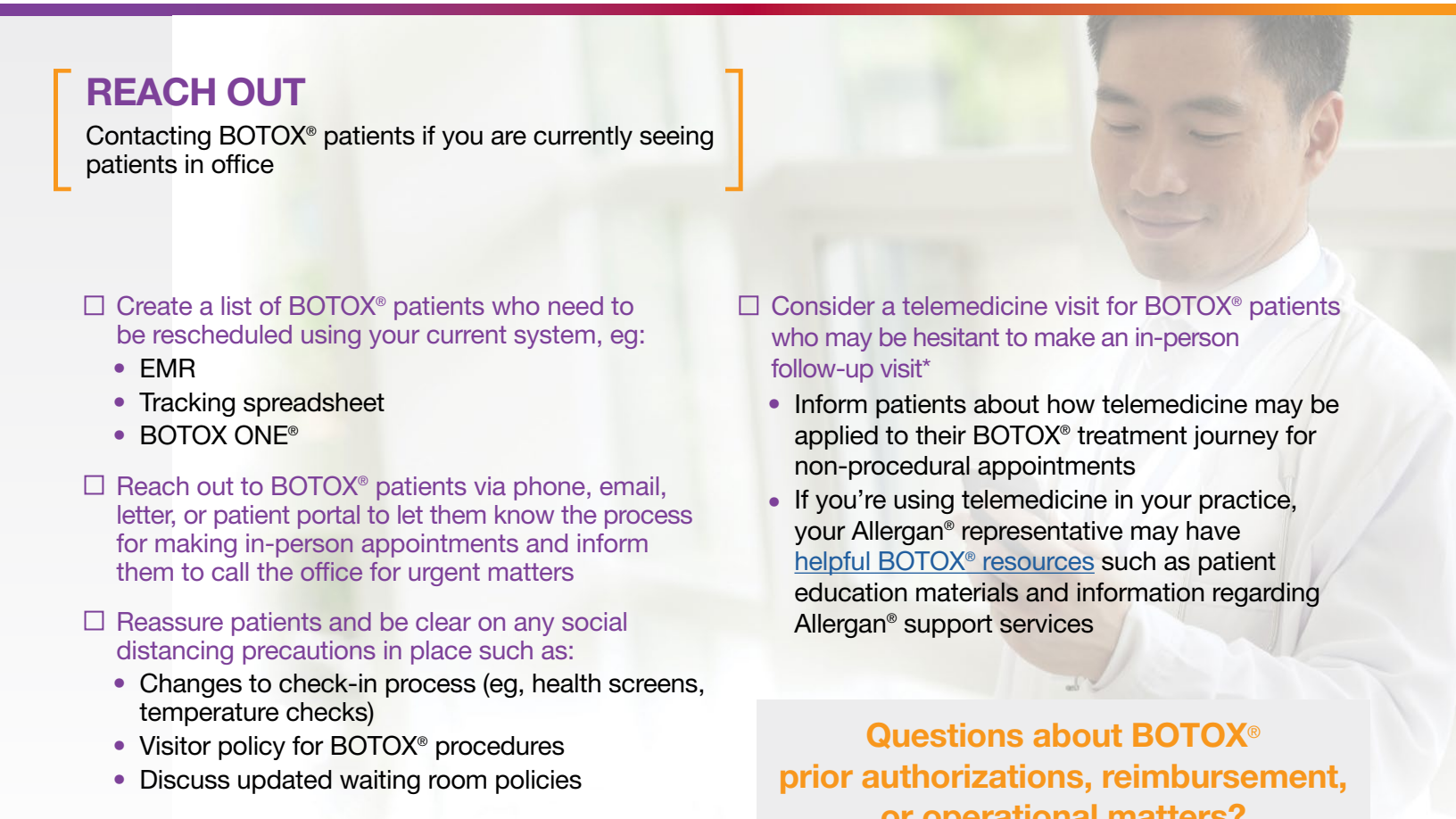
BOTOX® onabotulinumtoxinA injection

CONTINUING WITH BOTOX®

A Guide to Bringing Patients Back on Treatment

Considerations to help you care for BOTOX® patients following clinic restrictions due to social distancing



REACH OUT

Contacting BOTOX® patients if you are currently seeing patients in office

- ☐ Create a list of BOTOX® patients who need to be rescheduled using your current system, eg:
  - EMR
  - Tracking spreadsheet
  - BOTOX ONE®
- ☐ Reach out to BOTOX® patients via phone, email, letter, or patient portal to let them know the process for making in-person appointments and inform them to call the office for urgent matters
- ☐ Reassure patients and be clear on any social distancing precautions in place such as:
  - Changes to check-in process (eg, health screens, temperature checks)
  - Visitor policy for BOTOX® procedures
  - Discuss updated waiting room policies
- ☐ Consider a telemedicine visit for BOTOX® patients who may be hesitant to make an in-person follow-up visit*
  - Inform patients about how telemedicine may be applied to their BOTOX® treatment journey for non-procedural appointments
  - If you're using telemedicine in your practice, your Allergan® representative may have helpful BOTOX® resources such as patient education materials and information regarding Allergan® support services

Questions about BOTOX® prior authorizations, reimbursement, or operational matters?

Your Allergan® Reimbursement Business Advisor is available upon request for these matters.

*Coverage for telemedicine visits depends on each patient's insurance plan.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® 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, ptosis, dysphagia, dysphonia, 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 symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses and approved indications, cases of spread of effect have been reported at doses comparable to those used to treat Cervical Dystonia and spasticity and at lower doses.

Please see Indications and additional Important Safety Information on the following pages.

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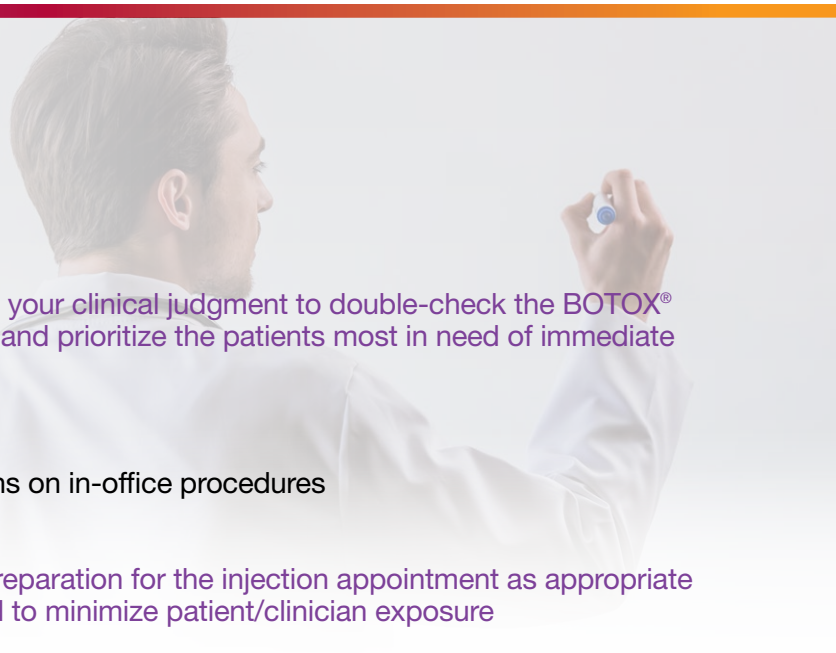

COORDINATE PATIENTS

Considerations for determining which BOTOX® patients may need retreatment sooner

☐ When reviewing the scheduling list you created, use your clinical judgment to double-check the BOTOX® retreatment recommendation per the BOTOX® label and prioritize the patients most in need of immediate retreatment, potentially factoring in:

- Severity and/or worsening of their condition
- Length of time since their last BOTOX® treatment
- Who has been on bridge therapy during restrictions on in-office procedures
- Date/week of last treatment or consultation

☐ Consider telephone/telemedicine consultations in preparation for the injection appointment as appropriate to help reduce time patients will be in the office, and to minimize patient/clinician exposure

Questions about BOTOX® prior authorizations, reimbursement, or operational matters?

Your Allergan® Reimbursement Business Advisor is available upon request for these matters.

Indications
Chronic Migraine
BOTOX® is indicated for the prophylaxis of headaches in adult patients with Chronic Migraine (≥ 15 days per month with headache lasting 4 hours a day or longer).

Limitations of Use
Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in 7 placebo-controlled studies.

Spasticity
BOTOX® is indicated for the treatment of spasticity in patients 2 years of age and older.

Limitations of Use
BOTOX® has not been shown to improve upper extremity functional abilities or range of motion at a joint affected by a fixed contracture.

IMPORTANT SAFETY INFORMATION (continued)
CONTRAINDICATIONS
BOTOX® is contraindicated in the presence of infection at the proposed injection site(s) and in patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation.

Please see additional Indications and Important Safety Information on the following pages.

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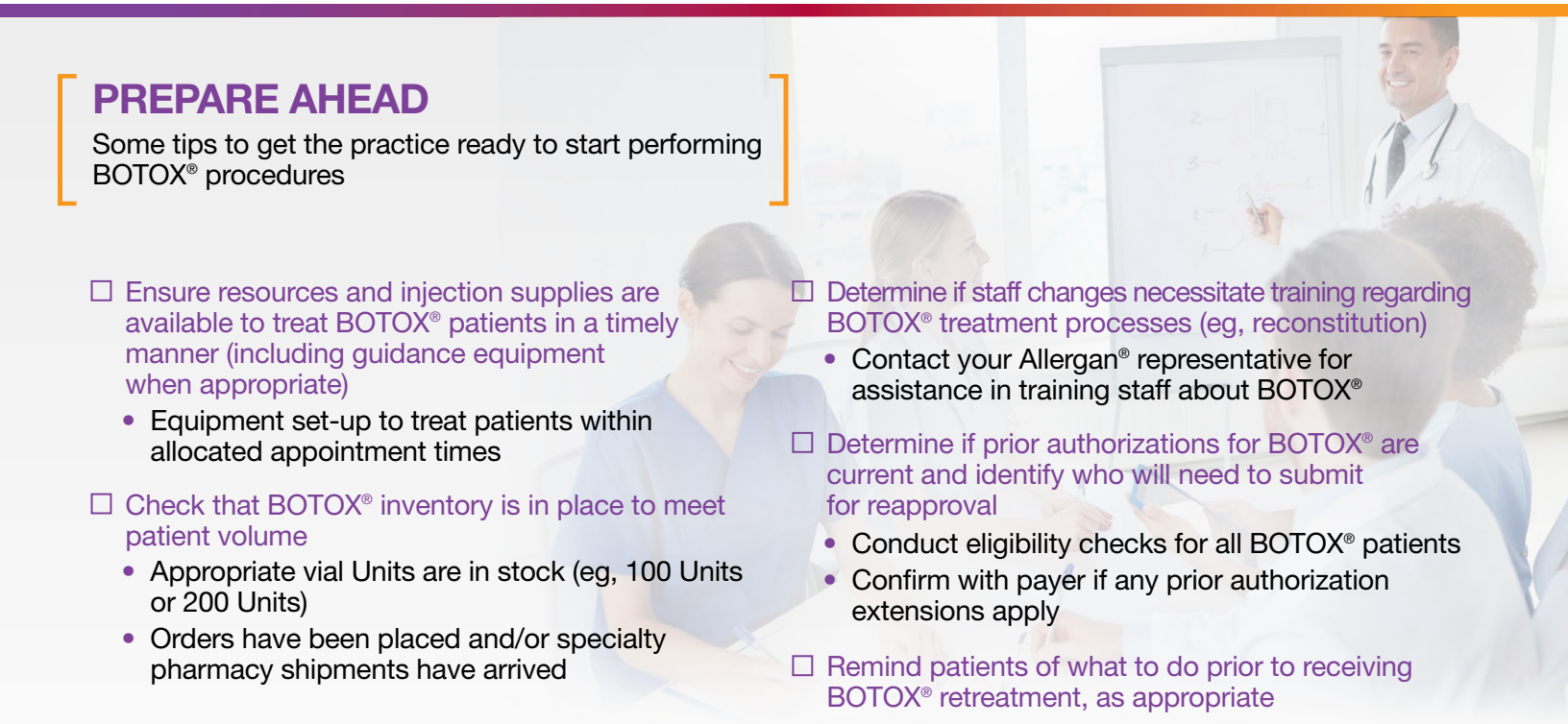

PREPARE AHEAD

Some tips to get the practice ready to start performing BOTOX® procedures

- ☐ Ensure resources and injection supplies are available to treat BOTOX® patients in a timely manner (including guidance equipment when appropriate)
  - Equipment set-up to treat patients within allocated appointment times
- ☐ Check that BOTOX® inventory is in place to meet patient volume
  - Appropriate vial Units are in stock (eg, 100 Units or 200 Units)
  - Orders have been placed and/or specialty pharmacy shipments have arrived
- ☐ Determine if staff changes necessitate training regarding BOTOX® treatment processes (eg, reconstitution)
  - Contact your Allergan® representative for assistance in training staff about BOTOX®
- ☐ Determine if prior authorizations for BOTOX® are current and identify who will need to submit for reapproval
  - Conduct eligibility checks for all BOTOX® patients
  - Confirm with payer if any prior authorization extensions apply
- ☐ Remind patients of what to do prior to receiving BOTOX® retreatment, as appropriate
- ☐ Encourage commercially insured patients to check eligibility for the BOTOX® Savings Program*

Questions about BOTOX® prior authorizations, reimbursement, or operational matters?

Your Allergan® Reimbursement Business Advisor is available upon request for these matters.

*By participating in the BOTOX ® Savings Program, you acknowledge and agree to the full Terms & Conditions set out at BOTOXSavingsProgram.com/TermsandConditions. Patients enrolled in Medicare, Medicaid, TRICARE, or any other government-reimbursed healthcare program are not eligible. Other restrictions and maximum limits apply.

Indications (continued)
Cervical Dystonia
BOTOX® is indicated for the treatment of adults with Cervical Dystonia to reduce the severity of abnormal head position and neck pain associated with Cervical Dystonia.

Blepharospasm and Strabismus
BOTOX® is indicated for the treatment of Strabismus and Blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS
Spread of Toxin Effect
See Boxed Warning.

No definitive serious adverse event reports of distant spread of toxin effect associated with BOTOX® for Blepharospasm at the recommended dose (30 Units and below), Strabismus, or for Chronic Migraine at the labeled doses have been reported.

Lack of Interchangeability Between Botulinum Toxin Products
The potency Units of BOTOX® 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 BOTOX® cannot be compared to nor converted into Units of any other botulinum toxin products assessed with any other specific assay method

Please see additional Important Safety Information on the following pages.

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CONTINUING WITH BOTOX®

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ADAPT PRACTICE

Considering ways to modify practice operations for potential volume changes in BOTOX® patient care and procedures

- ☐ Consider scheduling priority of BOTOX® patients based on the current situation
- ☐ Potentially use NPs/PAs to support follow-up telemedicine visits, as appropriate, to help free physicians for performing BOTOX® procedures
- ☐ Review room logistics and supplies for BOTOX® procedures
- ☐ Contact your Allergan® representative for more information about BOTOX®

Questions about BOTOX® prior authorizations, reimbursement, or operational matters?

Your Allergan® Reimbursement Business Advisor is available upon request for these matters.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Serious Adverse Reactions With Unapproved Use
Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Hypersensitivity Reactions
Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such a reaction occurs, further injection of BOTOX® should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently the causal agent cannot be reliably determined.

Increased Risk of Clinically Significant Effects With Pre-existing Neuromuscular Disorders
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with known or unrecognized neuromuscular disorders or neuromuscular junction disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from therapeutic doses of BOTOX® (see *Warnings and Precautions*).

Please see additional Important Safety Information on the following pages.

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A $1000 per treatment cap means ≈ 81% of BOTOX® patients enrolled in the BOTOX® Savings Program may pay $0[1,*]

*By participating in the BOTOX® Savings Program, you acknowledge and agree to the full Terms & Conditions set out at BOTOXSavingsProgram.com/TermsandConditions. Patients enrolled in Medicare, Medicaid, TRICARE, or any other government-reimbursed healthcare program are not eligible. Other restrictions and maximum limits apply.

BOTOX® SAVINGS PROGRAM

- Per treatment cap is $1000
- Annual treatment cap is $4000
- Applies to all BOTOX® Indications
- Learn more at BOTOXSavingsProgram.com

ALLERGAN® SUPPORT FOR YOU AND YOUR PRACTICE

Clinician and/or office staff resources

- Injection and reconstitution training and relevant materials (for clinicians only)
- BOTOX® Savings Program
- BOTOX® samples for appropriate new Chronic Migraine, Spasticity, or Cervical Dystonia patients
- BOTOX® ordering assistance
- Patient brochures

Scheduling personnel resources

- Retreatment guidelines
- Patient communication
- BOTOX® ordering assistance
- Patient brochures

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Dysphagia and Breathing Difficulties
Treatment with BOTOX® 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 oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Pulmonary Effects of BOTOX® in Patients With Compromised Respiratory Status Treated for Spasticity
Patients with compromised respiratory status treated with BOTOX® for spasticity should be monitored closely.

Please see additional Important Safety Information on the following pages.

BOTOX®
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OTHER PHONE NUMBERS AND WEBSITES

Ordering
AllerganDirect.com or call 1-800-44-BOTOX (1-800-442-6869)

Customer Service
1-800-44-BOTOX (1-800-442-6869)

Allergan® Medical Information Line
1-800-44-BOTOX (1-800-442-6869)

Patient Treatment Savings
For commercially insured patients: BOTOXSavingsProgram.com

Professional Education and Resources
For injection training opportunities: Contact your Allergan® representative
For Reimbursement Business Advisors: Contact your Allergan® representative
For injection and reconstitution videos, plus downloadable patient education and more:
Visit BOTOXAcademy.com or BOTOXMedical.com

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Corneal Exposure and Ulceration in Patients Treated With BOTOX® for Blepharospasm
Reduced blinking from BOTOX® injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect, and corneal ulceration, especially in patients with VII nerve disorders.

Retrobulbar Hemorrhages in Patients Treated With BOTOX® for Strabismus
During the administration of BOTOX® for the treatment of Strabismus, retrobulbar hemorrhages sufficient to compromise retinal circulation have occurred. It is recommended that appropriate instruments to decompress the orbit be accessible.

Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity
Bronchitis was reported more frequently as an adverse reaction in adult patients treated for upper limb spasticity with BOTOX® (3% at 251 Units to 360 Units total dose) compared to placebo (1%). In adult patients with reduced lung function treated for upper limb spasticity, upper respiratory tract infections were also reported more frequently as adverse reactions in patients treated with BOTOX® (11% at 360 Units total dose; 8% at 240 Units total dose) compared to placebo (6%). In adult patients treated for lower limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX® (2% at 300 Units to 400 Units total dose) compared to placebo (1%). In pediatric patients treated for upper limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX® (17% at 6 Units/kg and 10% at 3 Units/kg) compared to placebo (9%). In pediatric patients treated for lower limb spasticity, upper respiratory tract infection was not reported with an incidence greater than placebo.

Please see additional Important Safety Information on the following page.

BOTOX®
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IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Human Albumin and Transmission of Viral Diseases
This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical 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 viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

ADVERSE REACTIONS

Adverse reactions to BOTOX® for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Chronic Migraine
The most frequently reported adverse reactions following injection of BOTOX® for Chronic Migraine include neck pain (9%), headache (5%), eyelid ptosis (4%), migraine (4%), muscular weakness (4%), musculoskeletal stiffness (4%), bronchitis (3%), injection-site pain (3%), musculoskeletal pain (3%), myalgia (3%), facial paresis (2%), hypertension (2%), and muscle spasms (2%).

Adult Upper Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX® for upper limb spasticity include pain in extremity, muscular weakness, fatigue, nausea, and bronchitis.

Adult Lower Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX® for lower limb spasticity include arthralgia, back pain, myalgia, upper respiratory tract infection, and injection-site pain.

Pediatric Upper Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX® in pediatric upper limb spasticity include upper respiratory tract infection (includes upper respiratory tract infection and viral upper respiratory tract infection), injection-site pain, nausea, constipation, rhinorrhea, nasal congestion, and seizure (includes seizure and partial seizure).

Pediatric Lower Limb Spasticity
The most frequently reported adverse reactions following injection of BOTOX® in pediatric lower limb spasticity include injection-site erythema, injection-site pain, oropharyngeal pain, ligament sprain, skin abrasion, and decreased appetite.

Cervical Dystonia
The most frequently reported adverse reactions following injection of BOTOX® for Cervical Dystonia include dysphagia (19%), upper respiratory infection (12%), neck pain (11%), and headache (11%).

Blepharospasm
The most frequently reported adverse reactions following injection of BOTOX® for Blepharospasm include ptosis (21%), superficial punctate keratitis (6%), and eye dryness (6%).

Strabismus
The most frequently reported adverse events following injection of BOTOX® for Strabismus include ptosis (15.7%) and vertical deviation (16.9%).

Postmarketing Experience
Adverse reactions that have been identified during postapproval use of BOTOX® are discussed in greater detail in Postmarketing Experience (Section 6.3 of the Prescribing Information).

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin. There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

DRUG INTERACTIONS

Co-administration of BOTOX® and other agents interfering with neuromuscular transmission (eg, aminoglycosides, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another 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 BOTOX®.

Please see BOTOX® full Prescribing Information including Boxed Warning and Medication Guide.

Reference: 1. Data on file, Allergan, BOTOX® Savings Program 2020 Dollar Coverage.

Allergan
an AbbVie company

MIND
Migraine: Innovation Navigation Discovery ™