

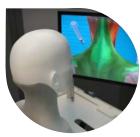
# **Dysport®**Resource Catalogue











# FDA-approved with more than a decade of clinical experience

FDA-approved for adult cervical dystonia in April 2009

### **INDICATIONS**

DYSPORT (abobotulinumtoxinA) for injection is indicated for the treatment of:

- spasticity in patients 2 years of age and older
- cervical dystonia in adults

### **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, 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 underlying conditions that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.

# **Surrounded by Support**

Whether you are new to Dysport or an experienced injector, Ipsen offers a wide range of educational and support resources for you, your practice, and your patients

# Get

# **Trained**

### **Extensive Resources**

Product information, injection simulators, eLearning modules, patient journey videos, and more at <a href="DysportHCP.com">DysportHCP.com</a>.

### **Peer-to-Peer Training**

In person, virtual, and on-demand programs to answer questions specific to Dysport. Visit <a href="DysportHCP.com">DysportHCP.com</a> or talk to your Ipsen representative for more information.

# Get

# **Started**

# **Injector Locator**

Make it easy for patients, caregivers, and referring physicians to find you through our <u>Injector Locator</u>.

### **IPSEN CARES®**

Coverage, access, reimbursement, and education support for you and your patients. Eligible, commercially insured patients may pay as little as \$0 per prescription.

Visit <u>IPSENCARES.com</u> for more information.\*

# Get

# Going

### **Product Acquisition**

Information on Dysport acquisition, coding, billing, and reimbursement.
See page 16 for more information.

### **Patient Resources**

Informative brochures for patients and parents/ caregivers about the management of spasticity or cervical dystonia.



<sup>\*</sup>See the patient eligibility terms and conditions for the Dysport copay assistance program on page 19



### **MENU**

# B.E.G.I.N. Workbook for Adult Spasticity and Cervical Dystonia Beginning Education to Guide Injection of Neurotoxins (B.E.G.I.N.) is a workbook designed to serve as an anatomy injection reference and practical guide to using Dysport. Anatomy & Injection Training Physical and Virtual Injection Simulators (S.A.D.I.E. and D.A.I.S.E.Y.) SynDaver<sup>™</sup> Limbs (synthetic cadavers) Anatomical Injection Training Models (AITMs) Patient, Ultrasound & Cadaver Videos MasterClass Anatomy and Injection Workshops Peer-to-Peer Education On-Demand Programs Live and Virtual Programs for Physicians and Their Staff MasterClass Anatomy and Injection Workshops See-One, Do-One Injection Training Important Safety Information for Dysport Dysport Resources for Physicians Product Information Clinical Overviews and Indication Briefs Patient Case Study Worksheets and Injection Records Dosing Reconstitution Preparing Your Practice With Dysport • Office Posters and Patient Injection Records • Electronic Health Records Guide Support for Product Acquisition, Coding, and Billing Patient Brochures **IPSEN CARES® Support for Providers** • Ipsen Resources and Support for Product Acquisition, Coding, and Billing

IPSEN CARES® for Patients

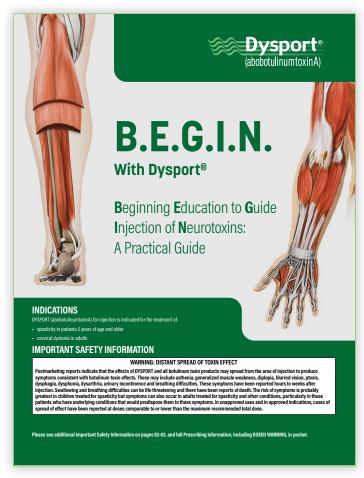
Coverage, Reimbursement, and Copay Assistance\*

<sup>\*</sup>Not applicable for federally funded healthcare.



# **B.E.G.I.N. WORKBOOK FOR ADULT SPASTICITY**

Beginning Education to Guide Injection of Neurotoxins (B.E.G.I.N.) is a workbook designed to serve as an anatomy injection reference and practical guide.



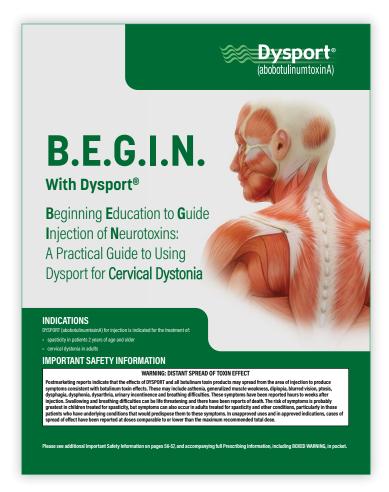






# **B.E.G.I.N. WORKBOOK FOR CERVICAL DYSTONIA**

Beginning Education to Guide Injection of Neurotoxins (B.E.G.I.N.) is a workbook designed to serve as an anatomy injection reference and practical guide for cervical dystonia.







# **ANATOMY & INJECTION TRAINING**

# **Injection Simulators**

Take your injection practice to the next level with S.A.D.I.E. (Spasticity Arm to Demonstrate Injection Education) and D.A.I.S.E.Y. (Dystonic Anatomical Injection Simulator Educating You)

These educational tools are used to visualize and target muscles using EMG technology and help learn Dysport dosing for the recommended muscles for upper limb spasticity and cervical dystonia.

### S.A.D.I.E. and D.A.I.S.E.Y.

Injection simulators for large group trainings and at major congresses

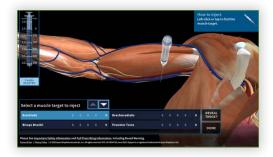




### Virtual S.A.D.I.E. and D.A.I.S.E.Y.

Please note, it is recommended that you are trained by an Ipsen representative prior to accessing the virtual S.A.D.I.E. and D.A.I.S.E.Y. tools





Also available with syringe stylus for a more tactile experience
In person with an Ipsen representative



To learn more, contact your Ipsen Neuroscience Sales Representative.

EMG=electromyography.



# Anatomy & Injection Training (continued)

# **Injection Simulators** (continued)

### **Upper and Lower SynDaver™ Limbs**

Realistic synthetic cadaver limbs, SynDaver mimics with high fidelity to reality the physical properties (e.g., resistance) of live tissues, to aid in the identification of topographical anatomic landmarks and provide a real-feel experience of an injection in the upper and lower limbs.

Contact your Ipsen representative for an expert-led guided course on relevant muscles, muscle anatomy (neuromuscular junction, end plates, insertion, origin, etc.), and functional anatomy related to spasticity.



# **Anatomical Injection Training Models (AITMs)**

3D silicone-based anatomical models designed for demonstrating and practicing injections for upper and lower limb spasticity, as well as cervical dystonia. These models are compatible with ultrasound imaging, providing partial needle visibility. This feature allows users to practice holding the ultrasound device with their non-dominant hand while manipulating the needle with their dominant hand.





To learn more, contact your Ipsen Neuroscience Sales Representative.



# Anatomy & Injection Training (continued)

# **Online and Downloadable Resources**

### **Patient Treatment Journey Videos**

Follow physicians and their patients with spasticity or cervical dystonia along their treatment journey with Dysport, including:

- Signs and symptoms
- Goal setting
- Injection

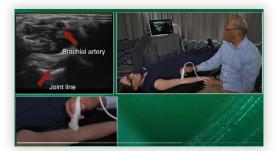
- Physical and occupational therapy
- Follow-up appointments
- Reinjection



### **Ultrasound Guidance Videos**

Learn how ultrasound can be used to identify muscles for injection in the lower limb, upper limb, and head/neck areas.





### **Anatomy & Injection Videos**

Videos using cadaver limbs to highlight anatomy of the muscles in the upper and lower limbs along with important injection technique and considerations.

Led by Dr David Porta and Dr Kimberly Heckert.









# **Anatomy & Injection Training**

# **Dysport MasterClass**

A Comprehensive, Hands-On, Injection Training Program Featuring Cadavers for Instruction and Injection Practice



Developed and led by expert faculty. Suitable for both new and experienced injectors.

### **Description:**

Hands-on learning and injection practice with expert faculty. Includes anatomy review of the upper and lower limb, or head and neck, using cadavers, education on proper injection techniques, and considerations for approved muscles for Dysport.

### **Curriculum:**

- Fully adaptable to audience and program needs/requirements
- Comprehensive one-day session or individual, sequenced components scheduled over time

### **Cost/Logistics:**

- · Attendance is FREE
- Flexibility to deliver at your institution or outside venue
- · Casual attire or scrubs recommended

This presentation is a Dysport promotional program provided by Ipsen Biopharmaceuticals, Inc. Presenters are speaking on behalf of Ipsen and are being compensated for their time. MasterClass is not a continuing medical education (CME) program.





# PEER-TO-PEER EDUCATION

# **Faculty-Led Educational Programs and Hands-On Learning**

Live educational sessions led by expert faculty are available to increase your knowledge and familiarity with Dysport. Programs are available for adult spasticity, pediatric spasticity, and cervical dystonia.



### **Virtual On Demands**

Expert answers questions on Dysport clinical data, dosing, and patient treatment during a 30 - 45-minute pre-scheduled teleconference



# MasterClass: Cadaver Anatomy and Injection Labs

Hands-on injection practice with expert faculty who review anatomy and educate on proper injection techniques and considerations for Dysport use



### **Group Speaker Programs**

Review the efficacy, safety, duration of response, and dosing of Dysport in a webinar or in-person presentation



### **Dysport Dialogue**

Case study-driven program focused on a facilitated discussion on goal setting, muscle and dose selection, and treatment planning for Dysport



### **Injection Training**

**See One:** In-person training where a visiting expert injector observes Dysport injections and receives coaching on clinical use by a speaker

**Do One:** In-person training where a speaker observes an expert injector administer Dysport injections, and offers coaching on dosing, technique, and clinical use



### **Ultrasound Programs**

Hands-on training and live demonstrations with expert faculty to enhance your Dysport injection skills through the use of ultrasound

To learn more, contact your Ipsen Neuroscience Sales Representative.



# **IMPORTANT SAFETY INFORMATION**

### **WARNING: DISTANT SPREAD OF TOXIN EFFECT**

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### **Contraindications**

DYSPORT is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow's milk protein, or to any of the components in the formulation, or infection at the proposed injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a serious reaction occurs, discontinue DYSPORT and institute appropriate medical therapy immediately.

### **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 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. Treatment of cervical dystonia with botulinum toxins may weaken accessory muscles of ventilation, which may result in a critical loss of breathing capacity in patients with respiratory disorders who may have become dependent upon these muscles. 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.



# **Important Safety Information** (continued)

### **Warnings and Precautions (continued)**

### **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 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, vCJD, or CJD 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 hyperhidrosis has not been established. DYSPORT is approved only for intramuscular injection.

### **Pre-existing Conditions at the Injection Site**

Caution should be exercised when DYSPORT is used where the targeted muscle shows excessive weakness or atrophy.

### **Adverse Reactions**

- The most common adverse reactions (≥4%) in adults with upper limb spasticity include muscular weakness; in adults with lower limb spasticity (≥5%) include falls, muscular weakness, and pain in extremity
- The most common adverse reactions (≥10%) in pediatric patients with upper limb spasticity include upper respiratory tract infection and pharyngitis; in pediatric patients with lower limb spasticity include nasopharyngitis, cough, and pyrexia
- The most common adverse reactions (≥5%) in adults with cervical dystonia include muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain, and eye disorders

### **Drug Interactions**

Co-administration of DYSPORT and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents) should only be performed with caution because the effect of the 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 and after administration of DYSPORT.



# DYSPORT RESOURCES FOR PHYSICIANS

# **Clinical Trial & Product Information**

### **Product Monographs**

A product overview including molecular structure, MOA, clinical history and data from pivotal trials for the 3 indications, recommended dosing and dilution, as well as storage and handling





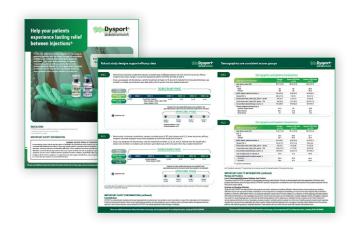
### **Clinical Overviews**

Provides detailed data from pivotal clinical trials including efficacy and safety profile as well as dosing recommendations.



### **Indication Briefs**

Indication-specific briefs that detail the study design, demographics, efficacy, and safety of Dysport studies.



To learn more, click here to visit <a href="DysportHCP.com">DysportHCP.com</a> or scan QR code.



MOA=mechanism of action.

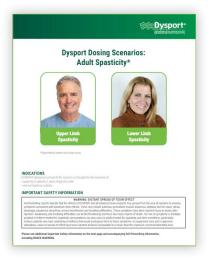


# Dysport Resources for Physicians (continued)

# **Clinical Trial & Product Information**

### **Case Study Worksheets**

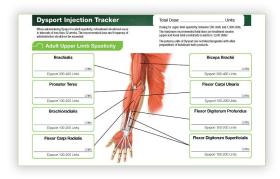
Hypothetical patient case studies to assist with Dysport dosing scenarios for spasticity and cervical dystonia.

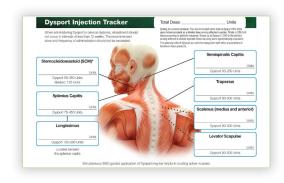




### **Patient Injection Records**

Injection records for the 3 indications that can be uploaded to EMR systems to record Dysport doses and muscles injected at each cycle.





To learn more, click here to visit <a href="DysportHCP.com">DysportHCP.com</a> or scan QR code.



EMR=electronic medical record.



# Dysport Resources for Physicians (continued)

# **Dosing and Dilution**

### **Dosing and Dilution Brochures**

Brochures with detailed muscles and FDA-approved doses for the treatment of adult patients with spasticity or cervical dystonia.

The pediatric brochure includes a weight-based dosing slider for the appropriate dosing of Dysport for your pediatric patients aged 2 years and older.





### **Reconstitution and Muscle Posters**

Visual aid of Dysport reconstitution and dilution instructions for your office.

Visual aid to review doses and muscles recommended for injection.



### **Reconstitution Practice**

Vehicle vials to practice appropriate Dysport reconstitution and dilution, experience partial vacuum, and develop injection skills with SynDavers or injection pods.

Reconstituted practice vials available by request.



Vial does not contain active ingredient

To learn more, click here to visit <u>DysportHCP.com</u> or scan QR code.



FDA=Food and Drug Administration.



# PREPARING YOUR PRACTICE WITH DYSPORT

### **Acquisition, Billing & Reimbursement**

The Dysport Reimbursement Resource Guide provides information on acquisition options for Dysport, billing and coding support, and an overview of IPSEN CARES® for copay and reimbursement.





### **Electronic Health Records Guide**

A flashcard that includes a step-by-step process for office staff on how to access Dysport in their EHR database.



# **Office Posters and Patient Injection Records**

Posters of Dysport dosing, reconstitution, and approved muscles for injection for quick reference at your office.

Injection records to help track Dysport units injected into each muscle. Billing and vial tracking information is also included to support your office staff.







# Preparing Your Practice With Dysport (continued)

### **Enroll Your Practice or Find a Dysport Injector**

The Dysport Injector Locator is an online search tool that is designed to make it easy for patients with spasticity or cervical dystonia, their caregivers, and referring physicians to find injectors in their area who are trained to administer Dysport.



Register to be listed at <a href="DysportHCP/Injector-Registration">DysportHCP/Injector-Registration</a>

### **Patient Brochures**

Informative brochures for patients and parents/caregivers about the management of spasticity or cervical dystonia. The brochures provide questions for patients to ask their doctors, goal-setting ideas, and what can be expected with Dysport treatment.









# **IPSEN CARES**

# Reimbursement and IPSEN CARES®

(Coverage, Access, Reimbursement & Education Support)

### **Acquisition, Coding, and Billing**

The Dysport Reimbursement Resource Guide provides information on acquisition, coding, coverage, and billing options for Dysport, and an overview of IPSEN CARES® for copay and reimbursement.





To learn more, click here to visit <a href="IPSENCARES.com">IPSENCARES.com</a> or scan QR code.





### **IPSEN CARES®**

### Reimbursement and IPSEN CARES® (continued)

(Coverage, Access, Reimbursement & Education Support)

### **Support for Eligible and Enrolled Patients Prescribed Dysport**

**Help patients navigate** the insurance coverage process to determine out-of-pocket costs

**Help with copay assistance** for eligible\* patients

**Provide free medication** to eligible<sup>†</sup> patients through the Patient Assistance Program

**Help minimize delays** or interruptions to treatment

Coordinate delivery of patient medication to HCP offices through specialty pharmacies



\*Patient Eligibility & Terms and Conditions: Patients are not eligible for copay assistance through IPSEN CARES® if they are enrolled in any state or federally funded programs for which drug prescriptions or coverage could be paid in part or in full, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA, DoD, or TRICARE (collectively, "Government Programs"), or where prohibited by law. Patients must be United States residents (including its territories) and enrolled in IPSEN CARES® to receive copay program benefits. Patients residing in Massachusetts or Rhode Island can only receive assistance with the cost of Ipsen products but not the cost of related medical services (injection). Patients receiving assistance through another assistance program or foundation, free trial, or other similar offer or program, are not eligible for the copay assistance program during the current enrollment year.

An annual calendar year maximum copay benefit applies. Patients may remain enrolled in copay assistance as long as eligibility criteria is met.

Patients or guardians are responsible for reporting receipt of copay savings benefit to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled through the program, as may be required. Additionally, patients or guardians may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, Health Reimbursement Account, or otherwise to a government or private payor. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or its copay assistance vendor are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. Claim reimbursement requests must be submitted within 180 days of treatment date. Data related to patient participation may be collected, analyzed, and shared with Ipsen for market research and other purposes related to assessing the program. Data shared with Ipsen will be de-identified, meaning it will not identify the patient. Void outside of the United States and its territories or where prohibited by law, taxed, or restricted. This program is not health insurance. No other purchase is necessary. Copay assistance cannot be sold, purchased, traded, or counterfeited. Void if reproduced.

<sup>†</sup>Patients may be eligible to receive free drug if they are experiencing financial hardship, have no insurance coverage, are US residents, and received a prescription for an on-label use of Dysport, as supported by information provided in the program application. Eligibility does not guarantee approval for participation in the program. The PAP provides Dysport product only, and does not cover the cost of previously purchased product or medical services.



Coverage, Access, Reimbursement & Education Support

IPSEN CARES is a registered trademark of Ipsen S.A. DYSPORT is a registered trademark of Ipsen Biopharm Limited. All other trademarks are the property of their respective owners.

To learn more, click here to visit <a href="IPSENCARES.com">IPSENCARES.com</a> or scan QR code.







Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-Unit vials.

DYSPORT is a registered trademark of Ipsen Biopharm Limited. IPSEN CARES is a registered trademark of Ipsen S.A.

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### Sample CMS-1500 Claim Form **Physician Office** Dysport\* (abobotulinumtoxinA) and the associated services provided in a physician's office are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 claim form for billing Dysport is provided below. The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information regarding their coding, coverage, and payment policies. Enter the appropriate ICD-10-CM diagnosis code, eg, G81.11 for spastic hemiplegia affecting right dominant side (upper limb spasticity). Code to the highest level of specificity. ICD-10-CM diagnosis codes contain 3-7 digits. It is recommen that providers verify each payer's specific coding requirements prior to injecting. Input the authorization For each code, insert the number if obtained from the insurance provider. number corresponding to the appropriate diagnosis code in field 21. Dysport, abobotulinumtoxinA G81.11 JZ Modifier N415054050001UN500.00 02 01 24 02 01 24 11 100 J0586 JZ 02 01 24 02 01 24 11 64642 A JW Modifier N415054050001UN500 00 02401 24 02 01 24 11 **▲**J0586 A 95 02 01 24 10 01 24 11 **Box 24D Box 24G** Report the appropriate number of units actually administered and the appropriate number of HCPCS units for Dysport J0586 (500-unit vial = 100 billing units, and 300-unit vial = 60 billing units). Please note, this n the shaded area, list the N4 qualifier, the 1-digit drug NDC#, the unit of measureme Include the appropriate CPT codes to report administration procedures, eg, 64642 (chemodeneryation of qualifier, and dosage. Example: 15054050001UN500.00 1 extremity, 1-4 muscle[s], eq. for upper limb spasticity). (Note: some payers may request the NDC number be listed in box 19.) For Dysport, use the unique HCPCS example shows usage of 475-unit vials code required by payer. Also, include appropriate modifiers as instructed In the non-shaded area, list the date of = 95 billing units and a wastage of 25-unit vials = 5 billing units. Note: For Dysport obtained through a specialty pharmacy, no charges for the drug should be billed by the provider. However, inclusion of the HCPCS code (J0586) is recommended to designate the drug administered and number of units administered. Consult with the individual payer to determine the appropriate method of documenting and billing for drugs obtained through a specialty pharmacy. The diagnosis and procedure codes listed on this sample claim form are provided as examples only Important Safety Information (Continued) Co-administration of Dysport and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents) should only be performed with caution because the effect of the 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 Please see additional Important Safety Information on pages 3-4 and accompanying full Prescribing Information, including BOXED WARNING. Dysport **IPSEN**CARES (abobotulinumtoxinA)

### 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, 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 underlying conditions that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to or lower than the maximum recommended total dose.