PATIENT INJECTION RECORD: ADULT SPASTICITY

Patient: _____ **Chart #:** _____

Date: _____ **Time:** _____

Complete the Dysport® (abobotulinumtoxinA) Injection Tracker below. For each muscle, indicate the dose used and the specific sites of injection.

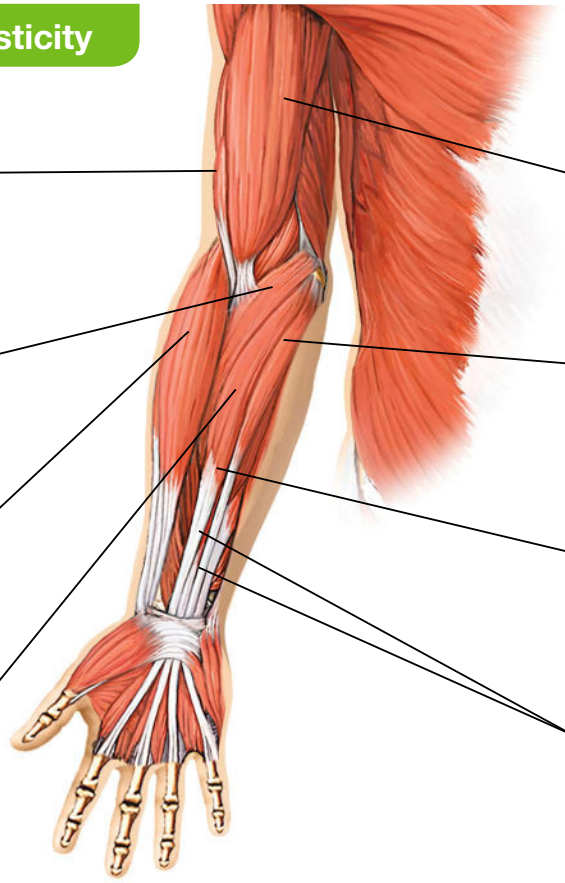
Dysport® Injection Tracker

Total Dose: _____ Units

Dosing for upper limb spasticity: between 500 Units and 1,000 Units
The maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1,500 Units

This Injection Record Form is designed to track Dysport® dosing Units and not to support muscle localization for injection.

Adult Upper Limb Spasticity



Brachialis
Units
Dysport® 200-400 Units

Biceps Brachii
Units
Dysport® 200-400 Units

Pronator Teres
Units
Dysport® 100-200 Units

Flexor Carpi Ulnaris
Units
Dysport® 100-200 Units

Brachioradialis
Units
Dysport® 100-200 Units

Flexor Digitorum Profundus
Units
Dysport® 100-200 Units

Flexor Carpi Radialis
Units
Dysport® 100-200 Units

Flexor Digitorum Superficialis
Units
Dysport® 100-200 Units

INDICATIONS

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

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

The safety and effectiveness of Dysport® injected into upper limb muscles or proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established.

Safety and effectiveness in pediatric patients with lower limb spasticity below 2 years of age have not been evaluated.

Safety and effectiveness in pediatric patients with cervical dystonia or upper limb spasticity have not been established.

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, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended total dose.

PATIENT INJECTION RECORD: ADULT SPASTICITY

Patient: _____ **Chart #:** _____

Date: _____ **Time:** _____

Complete the Dysport® (abobotulinumtoxinA) Injection Tracker below. For each muscle, indicate the dose used and the specific sites of injection.

Dysport® Injection Tracker

Total Dose: _____ Units

This Injection Record Form is designed to track Dysport® dosing Units and not to support muscle localization for injection.

Dosing for lower limb spasticity: up to 1,500 Units
The maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1,500 Units

Adult Lower Limb Spasticity

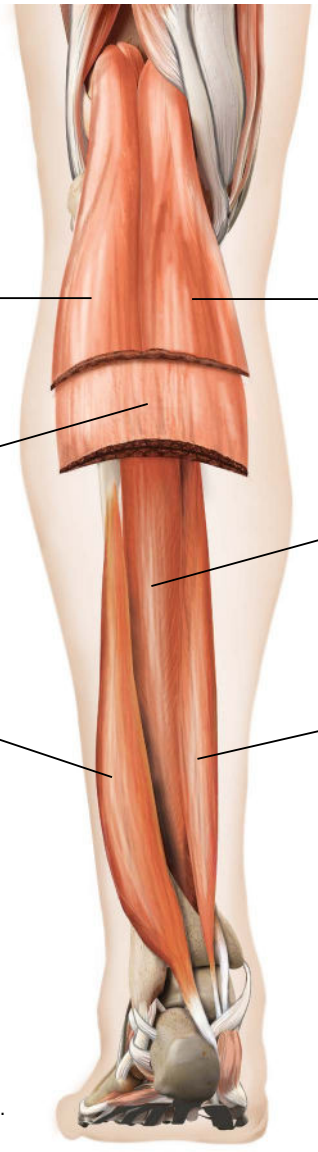


Image represents a left leg.

Gastrocnemius (Lateral head)
Units
Dysport® 100-150 Units

Gastrocnemius (Medial head)
Units
Dysport® 100-150 Units

Soleus
Units
Dysport® 330-500 Units

Tibialis Posterior
Units
Dysport® 200-300 Units

Flexor Hallucis Longus
Units
Dysport® 70-200 Units

Flexor Digitorum Longus
Units
Dysport® 130-200 Units

IMPORTANT SAFETY INFORMATION (continued)

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.

TRACKING AND BILLING: ADULT SPASTICITY

5 Dysport® Units Is 1 Billable Unit

Dysport® HCPCS Code	Description
J0586	Injection, abobotulinumtoxinA, 5 Units

500-Unit vial NDC 15054-0500-1*

Billing Units: 100

300-Unit vial NDC 15054-0530-6*

Billing Units: 60

*Please note that for billing purposes, the NDC number requires 11 digits. Therefore, a zero must be entered into the 10th position (eg, "15054-0500-01"). This is consistent with the Red Book and First DataBank listings.

Dysport® Units	
_____	Injected Units
_____	Wastage
_____	Billable Units
_____	Total Units†

†Divide by 5 = 1 Billable Unit.

The form is not intended to provide recommendations on clinical practice or legal advice. This document represents no statement, promise, or guarantee concerning coverage or levels of reimbursement. It is always the physician's or facility's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered.

Dysport® Product Tracking

Lot Number	Expiration Date
_____	_____
_____	_____
_____	_____
_____	_____

For CPT code information, please reference the Dysport® Resource Guide.

Additional notes: _____

_____

_____

Was EMG guidance performed?

☐ **Yes** ☐ **No** **Other method performed:** _____

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information on next page, and click here for Prescribing Information, including **Boxed Warning** regarding distant spread of toxin effect.

Dysport® (abobotulinumtoxinA) It's Time

INDICATIONS

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

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

The safety and effectiveness of Dysport® injected into upper limb muscles or proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established.

Safety and effectiveness in pediatric patients with lower limb spasticity below 2 years of age have not been evaluated.

Safety and effectiveness in pediatric patients with cervical dystonia or upper limb spasticity have not been established.

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, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended total dose.

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.

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 (see **Boxed Warning**). 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 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.

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.

Adverse Reactions

Most common adverse reactions (≥2% and greater than Placebo in either Dysport® group) **in adults with upper limb spasticity** for Dysport® 500 Units, Dysport® 1000 Units, and Placebo, respectively, were: nasopharyngitis (4%, 1%, 1%), urinary tract infection (3%, 1%, 2%), muscular weakness (2%, 4%, 1%), musculoskeletal pain (3%, 2%, 2%), dizziness (3%, 1%, 1%), fall (2%, 3%, 2%), and depression (2%, 3%, 1%).

Most common adverse reactions (≥5% and greater than placebo in either Dysport® group) **in adults with lower limb spasticity** for Dysport® 1000 Units, Dysport® 1500 Units, and Placebo, respectively, were: falls (9%, 6%, 3%), muscular weakness (2%, 7%, 3%), and pain in extremity (6%, 6%, 2%). Muscular weakness was reported more frequently in women (10%) treated with 1500 units of Dysport® compared to men (5%).

Most common adverse reactions (≥5% and greater than Placebo) **in adults with cervical dystonia** for Dysport® 500 Units and Placebo, respectively, were: muscular weakness (16%, 4%), dysphagia (15%, 4%), dry mouth (13%, 7%), injection site discomfort (13%, 8%), fatigue (12%, 10%), headache (11%, 9%), musculoskeletal pain (7%, 3%), dysphonia (6%, 2%), injection site pain (5%, 4%), and eye disorders (7%, 2%).

Most common adverse reactions (≥10% in any group and greater than Placebo) **in pediatric patients with lower limb spasticity** for Dysport® 10 Units/kg, 15 Units/kg, 20 Units/kg, or 30 Units/kg; and Placebo, respectively, were: upper respiratory tract infection (9%, 20%, 5%, 10%, 13%), nasopharyngitis (9%, 12%, 16%, 10%, 5%), influenza (0%, 10%, 14%, 3%, 8%), pharyngitis (5%, 0%, 11%, 3%, 8%), cough (7%, 6%, 14%, 10%, 6%), and pyrexia (7%, 12%, 8%, 7%, 5%).

Drug Interactions

Co-administration of Dysport® and aminoglycosides 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 and other drug therapy. Subjects aged 65 years and over who were treated with Dysport® for lower limb spasticity reported a greater percentage of fall and asthenia as compared to those younger (10% versus 6%, and 4% versus 2%, respectively).

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here to see Dysport® Full Prescribing Information, including **Boxed Warning** and Medication Guide.

Reference: Dysport® (abobotulinumtoxinA) [Prescribing Information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc; June 2017.

IPSEN
Innovation for patient care

Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-Unit vials.
DYSPORT is a registered trademark of Ipsen Biopharm Limited.
 October 2017 DYS-US-002344

Dysport® (abobotulinumtoxinA) It's Time

PATIENT INJECTION RECORD: ADULT SPASTICITY

Patient: _____ **Chart #:** _____

Date: _____ **Time:** _____

Complete the Dysport® (abobotulinumtoxinA) Injection Tracker below. For each muscle, indicate the dose used and the specific sites of injection.

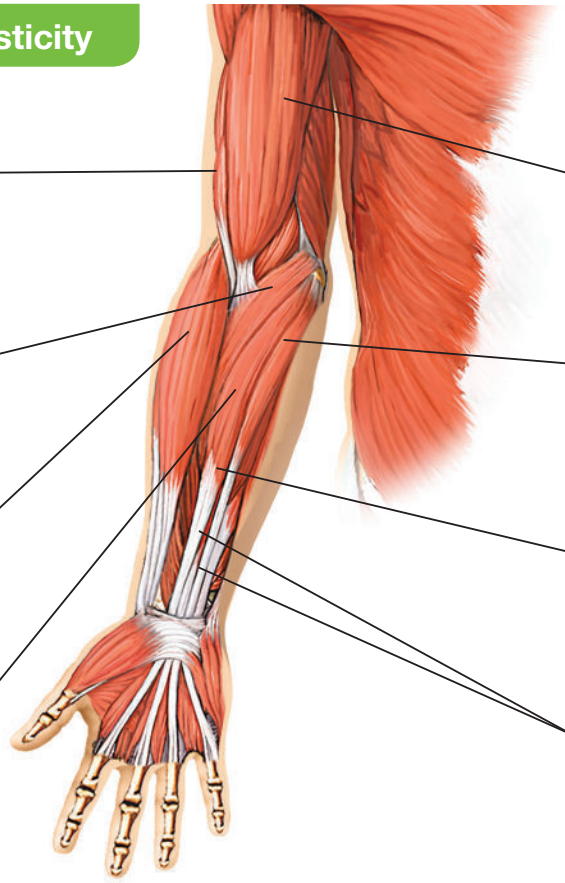
Dysport® Injection Tracker

Total Dose: _____ Units

Dosing for upper limb spasticity: between 500 Units and 1,000 Units
The maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1,500 Units

This Injection Record Form is designed to track Dysport® dosing Units and not to support muscle localization for injection.

Adult Upper Limb Spasticity



Brachialis
Units
Dysport® 200-400 Units

Biceps Brachii
Units
Dysport® 200-400 Units

Pronator Teres
Units
Dysport® 100-200 Units

Flexor Carpi Ulnaris
Units
Dysport® 100-200 Units

Brachioradialis
Units
Dysport® 100-200 Units

Flexor Digitorum Profundus
Units
Dysport® 100-200 Units

Flexor Carpi Radialis
Units
Dysport® 100-200 Units

Flexor Digitorum Superficialis
Units
Dysport® 100-200 Units

INDICATIONS

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

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

The safety and effectiveness of Dysport® injected into upper limb muscles or proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established.

Safety and effectiveness in pediatric patients with lower limb spasticity below 2 years of age have not been evaluated.

Safety and effectiveness in pediatric patients with cervical dystonia or upper limb spasticity have not been established.

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, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended total dose.

Please see additional Important Safety Information throughout this brochure, including **Boxed Warning**, and the accompanying Full Prescribing Information.

Dysport® (abobotulinumtoxinA)

It's Time

PATIENT INJECTION RECORD: ADULT SPASTICITY

Patient: _____ **Chart #:** _____

Date: _____ **Time:** _____

Complete the Dysport® (abobotulinumtoxinA) Injection Tracker below. For each muscle, indicate the dose used and the specific sites of injection.

Dysport® Injection Tracker

Total Dose: _____ Units

This Injection Record Form is designed to track Dysport® dosing Units and not to support muscle localization for injection.

Dosing for lower limb spasticity: up to 1,500 Units

The maximum recommended total dose per treatment session (upper and lower limb combined) in adults is 1,500 Units

Adult Lower Limb Spasticity

Gastrocnemius (Lateral head)

Units

Dysport® 100-150 Units

Soleus

Units

Dysport® 330-500 Units

Flexor Hallucis Longus

Units

Dysport® 70-200 Units

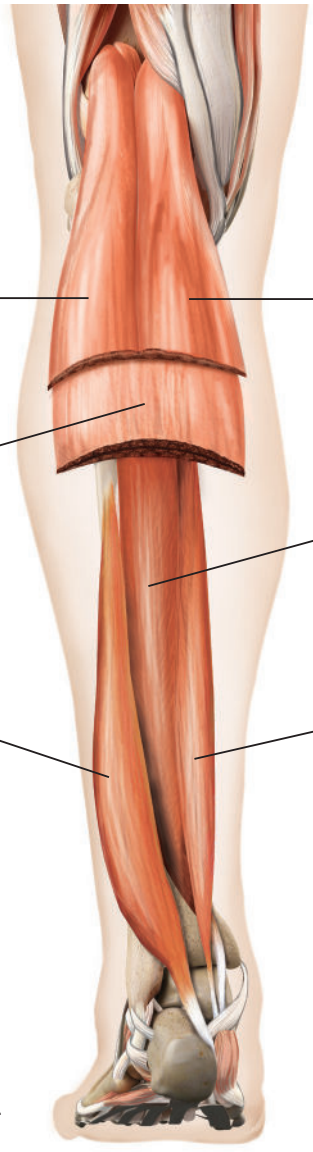


Image represents a left leg.

Gastrocnemius (Medial head)

Units

Dysport® 100-150 Units

Tibialis Posterior

Units

Dysport® 200-300 Units

Flexor Digitorum Longus

Units

Dysport® 130-200 Units

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout this brochure, including **Boxed Warning**, and the accompanying Full Prescribing Information.

Dysport® (abobotulinumtoxinA)

It's Time

TRACKING AND BILLING: ADULT SPASTICITY

5 Dysport® Units Is 1 Billable Unit

Dysport® HCPCS Code	Description
J0586	Injection, abobotulinumtoxinA, 5 Units

500-Unit vial NDC 15054-0500-1*

Billing Units: 100

300-Unit vial NDC 15054-0530-6*

Billing Units: 60

*Please note that for billing purposes, the NDC number requires 11 digits. Therefore, a zero must be entered into the 10th position (eg, "15054-0500-01"). This is consistent with the Red Book and First DataBank listings.

Dysport® Units	
_____	Injected Units
_____	Wastage
_____	Billable Units
_____	Total Units†

†Divide by 5 = 1 Billable Unit.

The form is not intended to provide recommendations on clinical practice or legal advice. This document represents no statement, promise, or guarantee concerning coverage or levels of reimbursement. It is always the physician's or facility's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered.

Dysport® Product Tracking

Lot Number	Expiration Date

For CPT code information, please reference the Dysport® Resource Guide.

Additional notes: _____

_____

_____

Was EMG guidance performed?

☐ **Yes** ☐ **No** **Other method performed:** _____

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout this brochure, including **Boxed Warning**, and the accompanying Full Prescribing Information.

Dysport® (abobotulinumtoxinA)

It's Time

INDICATIONS

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

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

The safety and effectiveness of Dysport® injected into upper limb muscles or proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established.

Safety and effectiveness in pediatric patients with lower limb spasticity below 2 years of age have not been evaluated.

Safety and effectiveness in pediatric patients with cervical dystonia or upper limb spasticity have not been established.

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, including upper limb spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to lower than the maximum recommended total dose.

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.

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 (see **Boxed Warning**). 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 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.

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.

Adverse Reactions

Most common adverse reactions (≥2% and greater than Placebo in either Dysport® group) **in adults with upper limb spasticity** for Dysport® 500 Units, Dysport® 1000 Units, and Placebo, respectively, were: nasopharyngitis (4%, 1%, 1%), urinary tract infection (3%, 1%, 2%), muscular weakness (2%, 4%, 1%), musculoskeletal pain (3%, 2%, 2%), dizziness (3%, 1%, 1%), fall (2%, 3%, 2%), and depression (2%, 3%, 1%).

Most common adverse reactions (≥5% and greater than placebo in either Dysport® group) **in adults with lower limb spasticity** for Dysport® 1000 Units, Dysport® 1500 Units, and Placebo, respectively, were: falls (9%, 6%, 3%), muscular weakness (2%, 7%, 3%), and pain in extremity (6%, 6%, 2%). Muscular weakness was reported more frequently in women (10%) treated with 1500 units of Dysport® compared to men (5%).

Most common adverse reactions (≥5% and greater than Placebo) **in adults with cervical dystonia** for Dysport® 500 Units and Placebo, respectively, were: muscular weakness (16%, 4%), dysphagia (15%, 4%), dry mouth (13%, 7%), injection site discomfort (13%, 8%), fatigue (12%, 10%), headache (11%, 9%), musculoskeletal pain (7%, 3%), dysphonia (6%, 2%), injection site pain (5%, 4%), and eye disorders (7%, 2%).

Most common adverse reactions (≥10% in any group and greater than Placebo) **in pediatric patients with lower limb spasticity** for Dysport® 10 Units/kg, 15 Units/kg, 20 Units/kg, or 30 Units/kg; and Placebo, respectively, were: upper respiratory tract infection (9%, 20%, 5%, 10%, 13%), nasopharyngitis (9%, 12%, 16%, 10%, 5%), influenza (0%, 10%, 14%, 3%, 8%), pharyngitis (5%, 0%, 11%, 3%, 8%), cough (7%, 6%, 14%, 10%, 6%), and pyrexia (7%, 12%, 8%, 7%, 5%).

Drug Interactions

Co-administration of Dysport® and aminoglycosides 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 and other drug therapy. Subjects aged 65 years and over who were treated with Dysport® for lower limb spasticity reported a greater percentage of fall and asthenia as compared to those younger (10% versus 6%, and 4% versus 2%, respectively).

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Ipsen at 1-855-463-5127. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Dysport® Full Prescribing Information, including **Boxed Warning** and Medication Guide.

Reference: Dysport® (abobotulinumtoxinA) [Prescribing Information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc; June 2017.

IPSEN
Innovation for patient care

Dysport® (abobotulinumtoxinA) for injection, for intramuscular use 300- and 500-Unit vials.
DYSPORT is a registered trademark of Ipsen Biopharm Limited.
 October 2017 Printed in USA DYS-US-002344

Dysport®
(abobotulinumtoxinA)

It's Time