

### **Choose Dysport for lasting symptom relief**<sup>1</sup>

- The minimum retreatment interval for pediatric upper limb spasticity is 16 weeks; however, most children in the trial did not receive their next injection for 16-28 weeks, giving them a chance for less frequent injections
- The minimum retreatment interval for pediatric lower limb spasticity is 12 weeks; however, most children in the trial did not receive their next injection for 16-22 weeks, giving them a chance for less frequent injections

### **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.

Please see additional Important Safety Information throughout this brochure, and accompanying full <u>Prescribing Information</u>, including **Boxed Warning** and <u>Medication Guide</u>.



# Meet Annika, a real pediatric patient living with spasticity

### Annika, 9 years old



Individual results may vary. Annika is a real Dysport patient. Annika was compensated for her appearance. Lives in Utah



Diagnosed with hemiplegic cerebral palsy at 18 months old

Guided through her treatment journey by her mother, Wendi

Receives occupational therapy every Thursday to complement her Dysport treatment

Wendi discovered Dysport through her own research

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## How Dysport helps Annika

### What Annika Wants From Treatment

What we really needed to work on was her walking. We were determined to find a doctor who listens and is willing to partner with us to reach our goals.

### **How Dysport Helps**

Annika moves smoother and faster. Her legs don't tire as quickly, and she doesn't have to work as hard to use the muscles.

-Wendi

-Wendi

### **Efficacy That Lasts**

My doctor gives me the Dysport and then she checks my flexibility about 6 weeks later. I get my injection about every 4 months.

-Annika

### **IMPORTANT SAFETY INFORMATION**

### Contraindications

Dysport is contraindicated in patients with known hypersensitivity to any botulinum toxin products, cow's milk protein, components in the formulation or infection at the injection site(s). Serious hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea have been reported. If such a 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.



## High-dose Dysport produced statistically significant results vs low-dose Dysport



### **PEDIATRIC UPPER LIMB**



### High-dose Dysport significantly loosened muscles at Week 61

• At Week 6, patients receiving 16 Units/kg demonstrated a significant reduction in muscle tone versus those receiving 2 Units/kg

#### Study design

The efficacy and safety of Dysport were evaluated in a multicenter, prospective, double-blind, randomized, low-dose controlled study assessing Dysport in pediatric patients 2 to 17 years of age with upper limb spasticity because of cerebral palsy. Patients were randomized to receive Dysport 2 Units/kg (n=70), 8 Units/kg (n=70), or 16 Units/kg (n=70) for the first treatment cycle. The completion of 1 cycle occurred when the patient received the next injection. The primary efficacy endpoint was mean change from baseline in muscle tone at Week 6, assessed by MAS in the PTMG. Secondary efficacy endpoints were mean change in the PGA at Week 6, and mean GAS score at Week 6. Patients were assessed for retreatment eligibility at Week 16. If ineligible for retreatment, they were evaluated every 6 weeks (plus or minus 2 weeks) until eligible. There had to be a minimum of 16 weeks between each injection session, and patients could receive a maximum of 4 sessions over the course of the study, which had a duration of up to 1 year and 9 months for each patient. After completing their first treatment cycle, patients receiving Dysport 2 Units/kg were re-randomized to receive Dysport 8 Units/kg) or down was mandated by the investigator. The study remained double blind for the remaining 3 cycles.<sup>12</sup>

### **IMPORTANT SAFETY INFORMATION**

### Warnings and Precautions (continued)

### **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.

Please see additional Important Safety Information throughout this brochure, and accompanying full **Prescribing Information**, including **Boxed Warning** and **Medication Guide**.

## Dysport offered lasting relief through the minimum 12-week retreatment time



### PEDIATRIC LOWER LIMB

### Dysport significantly loosened muscles at Week 4 and Week 12<sup>1</sup>



The investigator graded muscle tone on a 6-point scale, from 0 (no increase in tone) to 4 (affected parts rigid in flexion or extension).<sup>2</sup> The co-primary efficacy endpoints were the

mean change in MAS score in the ankle plantar flexor and the mean PGA of response to treatment between baseline and Week 4.1

## Children on Dysport had a significantly greater response to treatment as assessed by PGA at Week 4 and Week 12<sup>1</sup>

- PGA score at Week 4: Dysport 10 Units/kg/leg=1.5; Dysport 15 Units/kg/leg=1.5; placebo=0.7 (P<0.05)
- PGA score at Week 12: Dysport 10 Units/kg/leg=0.8; Dysport 15 Units/kg/leg=1.0; placebo=0.4 (P<0.05)

#### Study design

The efficacy and safety of Dysport were evaluated in a multicenter, prospective, double-blind, randomized, placebo-controlled study assessing Dysport in pediatric patients 2 to 17 years of age with lower limb spasticity because of cerebral palsy causing dynamic equinus foot deformity. In the pivotal clinical study, doses of Dysport 10 Units/kg/leg, Dysport 15 Units/kg/leg, or placebo were injected intramuscularly into the gastrocnemius and soleus muscles. The 12-week follow-up visit included assessment for retreatment eligibility. Pediatric patients who remained in the study after Week 12 were permitted additional discretionary follow-up visits at Week 16, Week 22, and Week 28 to assess eligibility for retreatment. Patients eligible for retreatment were eligible for enrollment into an open-label extension study lasting up to a year or 4 treatment cycles.<sup>1,2</sup>

### **IMPORTANT SAFETY INFORMATION**

### 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.



# For many patients, the effect of Dysport lasted beyond the minimum retreatment period

## A majority of patients did not need retreatment until Weeks 16-28; however, some had a longer duration of response<sup>1,2\*</sup>



• Out of the patients receiving Dysport 8 Units/kg, 15.8% were retreated between Weeks 34 and 52. Of that number, 3 patients were withdrawn, while 6 did not need a reinjection, or data was missing<sup>2</sup>

• Out of the patients receiving Dysport 16 Units/kg, 20% were retreated between Weeks 34 and 52. Of that number, 3 patients were withdrawn, while 7 did not need a reinjection, or data was missing<sup>2</sup>

## A majority of patients did not need retreatment until Weeks 16-22; however, some had a longer duration of response<sup>1,2†</sup>



- The optimal dose of Dysport, muscles to be injected, and retreatment eligibility should be selected based on the patient's progress and response to treatment<sup>1,2</sup>
- Retreatment for upper limb spasticity should occur no sooner than 16 weeks after the first injection<sup>1</sup>
- Retreatment for lower limb spasticity should occur no sooner than 12 weeks after the first injection<sup>1</sup>
- Eligibility for retreatment was assessed by the investigator at every visit onward from Week 12 for lower limb spasticity or Week 16 for upper limb spasticity<sup>2</sup>

\*Patients who remained in the upper limb study after Week 16 were permitted additional discretionary follow-up visits at Week 22, Week 28, Week 34, or beyond.<sup>3</sup> \*Patients who remained in the lower limb study after Week 12 were permitted additional discretionary follow-up visits at Week 16, Week 22, and Week 28 to assess eligibility for retreatment.<sup>3</sup>

<sup>‡</sup>4.4% of patients were retreated after Week 28.<sup>2</sup>

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## Goal Attainment Scores at Week 4 and Week 12

PEDIATRIC LOWER LIMB

### GAS results at Week 4 and Week 12<sup>2</sup>

• Both Dysport doses achieved statistically significant improvement in GAS (secondary endpoint) vs placebo<sup>2</sup>

## **RESPONDER ANALYSES FOR ACHIEVEMENT OF PRIMARY GOAL AND FOR THE 5 MOST COMMONLY CHOSEN INDIVIDUAL GOALS (TERTIARY ENDPOINT)\***<sup>4</sup>

	Placebo (n=77), %	Dysport 10 U/kg/leg (n=79), %	Dysport 15 U/kg/leg (n=79), %
Primary goal achievement	62	79	76
ndividual goal analysis			
Improved walking pattern			
Responder rate Week 4	40	79	60
Responder rate Week 12	39	72	63
Improved balance			
Responder rate Week 4	53	62	39
Responder rate Week 12	56	62	56
Decreased frequency of falling			
Responder rate Week 4	56	82	69
Responder rate Week 12	42	90	71
Decreased frequency of tripping			
Responder rate Week 4	46	56	77
Responder rate Week 12	62	64	88
Improved endurance			
Responder rate Week 4	55	72	64
Responder rate Week 12	46	88	91

GAS=Goal Attainment Scale.

\*Best goal attainment total score for each patient was assessed using the best score attained for each goal at any time during the study. Patients who completed the study or withdrew are counted as missing at subsequent visits.

## IMPORTANT SAFETY INFORMATION

### 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.

### **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 as reported in pediatric patients receiving Dysport up to 16 Units/kg

### PEDIATRIC UPPER LIMB

# Adverse reactions observed in ≥3% of patients treated in the double-blind study of pediatric patients with upper limb spasticity that were reported more frequently than in the control group<sup>1</sup>

Adverse Reactions	Dysport 2 Units/kgª (n=70), %	Dysport 8 Units/kg (n=70), %	Dysport 16 Units/kg (n=70), %
Infections and infestations			
Upper respiratory tract infection	7	9	11
Influenza	1	1	3
Pharyngitis <sup>b</sup>	9	6	10
Gastrointestinal disorders			
Nausea	0	3	1
Musculoskeletal and connective tissue disorders			
Muscular weakness	1	4	6
Nervous system disorders			
Headache	0	6	3
Epilepsy	1	0	4
			and the second se

<sup>a</sup>Low dose active comparator arm.

<sup>b</sup>Includes pharyngitis, pharyngitis streptococcal, pharyngotonsillitis.

Additional adverse reactions occurring below 3% and considered to be drug related include: myalgia, pain in extremity, fatigue, influenza-like illness, injection site eczema, injection site bruising, injection site rash, injection site pain, and injection site swelling.

ADR=adverse drug reaction.

### **IMPORTANT SAFETY INFORMATION**

### **Most Common Adverse Reactions**

Adults with lower limb spasticity ( $\geq$ 5%): falls, muscular weakness, and pain in extremity and with upper limb spasticity ( $\geq$ 4%): muscular weakness.

**Pediatric patients with lower limb spasticity** (≥10%): nasopharyngitis, cough and pyrexia and with **upper limb spasticity** (≥10%): upper respiratory tract infection and pharyngitis.

**Adults with cervical dystonia** (≥5%): 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), 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.

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# Adverse reactions as reported in pediatric patients receiving Dysport up to 30 Units/kg

PEDIATRIC LOWER LIMB

Adverse reactions observed in ≥4% of patients treated in the double-blind trial of pediatric patients with lower limb spasticity reported more frequently than with placebo<sup>1</sup>

Adverse Reactions		Unilateral Injections		Bilateral Injections	
	Placebo (n=79), %	Dysport 10 Units/kg (n=43), %	Dysport 15 Units/kg (n=50), %	Dysport 20 Units/kg (n=37), %	Dysport 30 Units/kg (n=30), %
Infections and infestations					
Nasopharyngitis	5	9	12	16	10
Bronchitis	3	0	0	8	7
Respiratory, thoracic, and mediastinal disorder	S				
Cough	6	7	6	14	10
General disorders and administration site cond	litions				
Pyrexia	5	7	12	8	7
Musculoskeletal and connective tissue disorde	ers				
Pain in extremity	5	0	2	5	7
Nervous system disorders					
Convulsion/epilepsy*	0	7	4	0	7

## **Open-label study safety results**

• In the open-label phase, the SOCs (and PTs) most frequently associated with TEAEs were infections and infestations (nasopharyngitis in 21.9% of subjects, upper respiratory tract infection in 21.4% of subjects, and pharyngitis in 11.6% of subjects); followed by general disorders and administration site conditions (pyrexia in 15.8% of subjects); respiratory, thoracic, and mediastinal disorders (cough in 9.3% of subjects); and gastrointestinal disorders (diarrhea in 7.4% of subjects)<sup>2</sup>

### **IMPORTANT SAFETY INFORMATION**

### **Special Populations**

### **Use in Pregnancy**

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. Based on animal data, Dysport may cause fetal harm.

### **Pediatric Use**

The safety and effectiveness of Dysport injected into proximal muscles of the lower limb for the treatment of spasticity in pediatric patients has not been established. 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% vs. 6% and 4% vs. 2%, respectively).

\*Convulsion/Epilepsy: five patients reported seizures in the double-blind study. Two of the cases occurred in the Dysport 10 Units/kg/leg group, and 3 occurred in the 15 Units/kg/leg group. Of the 5 reported cases, only 1 was a new occurrence of epilepsy (in the 10 Units/kg/leg group). All cases were considered unrelated to study treatment.<sup>3</sup>



PT=preferred term; SOC=primary system organ class; TEAE=treatment emergent adverse event.

## **Choose Dysport for lasting relief** in pediatric spasticity

### Reduction in muscle tone in both upper and lower limb spasticity<sup>1</sup>

- For children with upper limb spasticity, the reduction in MAS lasted through Week 6
- For children with lower limb spasticity, the reduction in MAS lasted through Week 12

### 4 to 6<sup>1</sup>/<sub>2</sub> months between treatments for most patients

- The minimum retreatment interval for pediatric upper limb spasticity is 16 weeks; however, most children in the trial did not receive their next injection for 16-28 weeks, giving them a chance for less-frequent injections<sup>1</sup>
- The minimum retreatment interval for pediatric lower limb spasticity is 12 weeks; however, most children in the trial did not receive their next injection for 16-22 weeks, giving them a chance for less-frequent injections<sup>1</sup>

### Safety assessed in 370 pediatric patients treated with Dysport<sup>1</sup>

- The most commonly observed adverse reactions in the upper limb spasticity trial ( $\geq$ 10% of patients) were: upper respiratory tract infection and pharyngitis
- The most commonly observed adverse reactions in the lower limb spasticity trial ( $\geq$ 10% of patients) were: upper respiratory tract infection, nasopharyngitis, influenza, pharyngitis, cough and pyrexia
  - To calculate the FDA-approved dose range for your patient, download the Dysport Dosing Guide from the Apple App Store or Google Play Store.

### 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.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact lpsen 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 additional Important Safety Information throughout this brochure, and accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

References: 1. Dysport® (abobotulinumtoxinA) [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; July 2020. 2. Data on file. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. 3. Delgado MR, Tilton A, Russman B, et al. AbobotulinumtoxinA for equinus foot deformity in cerebral palsy: a randomized controlled trial. Pediatrics. 2016;137(2) e20152830. doi: 10.1542/peds.2015-2830. 4. Tilton A, Russman B, Aydin R, et al. AbobotulinumtoxinA (Dysport) improves function according to goal attainment in children with dynamic equinus due to cerebral palsy. J Child Neurol. 2017;32(5):482-487.



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## Dysport offers comprehensive support and resources for your patients

## Start your Dysport experience by utilizing key resources with the help of a



### For your practice:



### Product acquisition

A specialist can provide assistance with acquiring Dysport for your practice.



### C.L.I.M.B.® hands-on injection training

This comprehensive injection training program for Dysport includes in-office training, live group training or web conferences (for dosing, reconstitution, and injection simulation), educational videos, and brochures.

### For your patients:



### **IPSEN CARES®** support program

The IPSEN CARES program offers support to your patients, including services such as benefits verification in as little as 1 business day.



### Copay program for eligible\* patients

IPSEN CARES also provides copay assistance to eligible patients, up to a maximum annual benefit of \$5,000.



### **Reimbursement assistance**

Eligible patients can be given reimbursement assistance.

\*Please see terms and conditions on the following page.



# Broad regional and national coverage for patients on Dysport

### **National Coverage Without Restrictions**

Adult Spasticity	Adult Cervical Dystonia	Pediatric Spasticity
97%	97%	92%

This document represents the percentage of patient lives covered for Dysport, however, there is no promise or guarantee concerning coverage or levels of reimbursement. It is recommended that you contact your local payers with regard to local reimbursement policies and practices. Please consult your counsel or reimbursement specialist on reimbursement or billing questions specific to your practice. **Coverage data provided by MMIT Analytics and current as of March 2020.** 

## The Dysport Copay Assistance Program



#### Eligible\* patients can pay as little as \$0 per prescription.

- Program exhausts after 4 injection treatments, or a maximum annual copay benefit of \$5,000, whichever comes first
- Program resets every January 1st
- Patients must enroll every 12 months from the date of acceptance to remain eligible to receive a continued benefit



#### 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 residing in Massachusetts, Minnesota, Michigan, 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.

Cash-pay patients are eligible to participate. "Cash-pay" patients are defined for purposes of this program as patients without insurance coverage or who have commercial insurance that does not cover Dysport<sup>®</sup>. Medicare Part D enrollees who are in the prescription drug coverage gap (the "donut hole") are not considered cash-pay patients and are not eligible for copay assistance through IPSEN CARES<sup>®</sup>. For patients with commercial insurance who are not considered to be cash-pay patients, the maximum copay benefit amount per prescription is an amount equal to the difference between the annual maximum copay benefit of \$5,000 and the total amount of copay benefit provided to the patient in the Dysport<sup>®</sup> Copay Program. In any calendar year commencing January 1, the maximum copay benefit amount paid by Ipsen Biopharmaceuticals, Inc. will be \$5,000, covering no more than four (4) Dysport® treatments. For cash-pay patients, the maximum copay benefit amount per eligible Dysport® treatment is \$1,250, subject to the annual maximum of \$5,000 in total. There could be additional financial responsibility depending on the patient's insurance plan. Patient or guardian is 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 may not submit any benefit provided by this program for reimbursement through a Flexible Spending Account, Health Savings Account, or Health Reimbursement Account. Ipsen reserves the right to rescind, revoke, or amend these offers without notice at any time. Ipsen and/or RxCrossroads by McKesson are not responsible for any transactions processed under this program where Medicaid, Medicare, or Medigap payment in part or full has been applied. 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 purchase is necessary.

Visit www.ipsencares.com for eligibility terms and conditions and additional copay information.



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