



Jill is a real patient living with PBA.

**NUEDEXTA<sup>®</sup>**  
(dextromethorphan HBr and 20 mg  
quinidine sulfate) capsules 10 mg

# PBA Treatment Guide

**Inside: Get the most from treatment with NUEDEXTA**

**NUEDEXTA is the first and only FDA-approved treatment for PBA.**

PBA is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury. PBA episodes are typically exaggerated or don't match how the person feels.

PBA is distinct and different from other types of emotional changes caused by neurologic disease or injury.

NUEDEXTA is only available by prescription.

## **IMPORTANT SAFETY INFORMATION:**

### **Before you take NUEDEXTA, tell your doctor:**

- If you are taking monoamine oxidase inhibitors (MAOIs), quinidine, or quinidine-related drugs. These can interact with NUEDEXTA causing serious side effects. MAOIs cannot be taken within 14 days before or after taking NUEDEXTA.

**Please see additional Important Safety Information on the following pages.**



Sequena is a real patient living with PBA.

# Treating Your PBA

Pseudobulbar Affect (PBA) is a medical condition that causes sudden, frequent, uncontrollable episodes of crying and/or laughing that is exaggerated or doesn't match how you feel. PBA may be caused by neurological damage related to your primary neurologic condition or brain injury but is a separate and treatable condition.

Since PBA episodes are unpredictable and can happen at inappropriate times, including in social situations, they can leave you feeling misunderstood and frustrated. The good news is that there is a treatment for PBA.



In a **12-week** clinical trial of **326 PBA patients** with amyotrophic lateral sclerosis or multiple sclerosis that measured average daily episode rate vs. placebo, patients taking NUEDEXTA experienced an average of **3.9 fewer episodes per day** compared with **6.8 episodes per day** before taking NUEDEXTA.

Patients taking placebo experienced an average **3.0 fewer episodes per day** compared with **4.5 episodes per day** before taking placebo.

Individual results may vary.

## IMPORTANT SAFETY INFORMATION (continued):

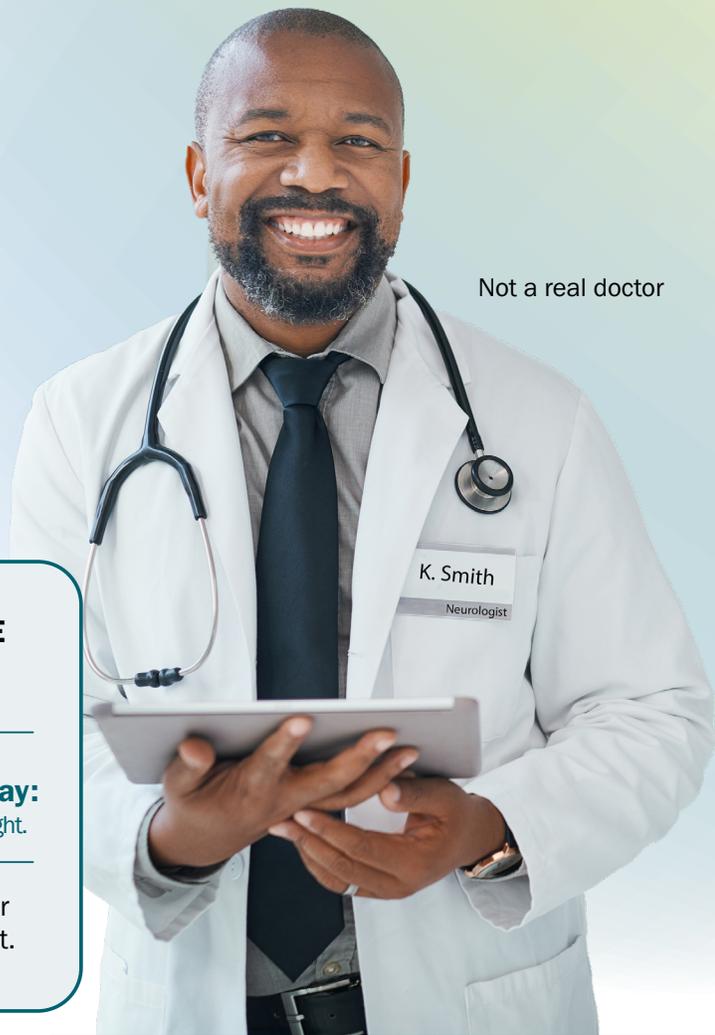
### Before you take NUEDEXTA, tell your doctor:

- If you have previously had an allergic reaction to dextromethorphan, quinidine or quinidine-like drugs.
- About all medicines, herbal supplements, and vitamins you take as NUEDEXTA and certain other medicines can interact causing side effects.

Please see additional Important Safety Information on the following pages.

# Getting Started on NUEDEXTA

You and your doctor have made the important decision to treat your PBA with NUEDEXTA, the first and only treatment approved by the FDA to treat PBA. As you continue your treatment, it's important to follow your dosing routine and give NUEDEXTA time to work.



## STARTING DOSE Days 1-7



**Take 1 capsule**  
each morning.

This dose introduces  
NUEDEXTA to your body.

## MAINTENANCE DOSE Beginning Day 8



**Take 2 capsules each day:**  
one in the morning and one at night.

This is your daily dose for  
the rest of your treatment.

## Important Dosing Guidelines

Here are some important things to know about treatment with NUEDEXTA.

- You can take NUEDEXTA with or without food.
- If you miss a dose, do not take a double dose. Take your next dose of NUEDEXTA at your usual time.
- Do not take more than 2 capsules in a 24-hour period. Make sure that you have approximately 12 hours in between your doses.

*“For me, having a PBA diagnosis and then having a treatment truly makes a difference.”*

**Mary-Beth**  
Patient living with epilepsy and PBA



### IMPORTANT SAFETY INFORMATION (continued):

**Before you take NUEDEXTA, tell your doctor:**

- If you have had heart disease or have a family history of heart rhythm problems. NUEDEXTA may cause serious side effects, including changes in heart rhythm. If you have certain heart problems, NUEDEXTA may not be right for you. Your doctor may test your heart rhythm (heartbeats) before you start NUEDEXTA.
- If you have myasthenia gravis.

Please see additional Important Safety Information on the following pages.



“Once I started to take NUEDEXTA, I definitely noticed a decrease in my PBA episodes.”

**Carol** | Patient living with traumatic brain injury and PBA

# Follow Your Doctor’s Advice

Trust the advice of your doctor and follow their instructions to see the best results with NUEDEXTA.



## Give Your Treatment Time

Remember, it can take time to see reduced PBA symptoms while taking NUEDEXTA. Taking your medication as prescribed can give you the best chance to start seeing a reduction in episodes.



## Stay Consistent

When you take the prescribed dose at the same time each day, you are keeping the right amount of medicine in your system, which allows it to work properly.



## Share Your Progress

Track your progress from day one of taking NUEDEXTA so you can share with your doctor detailed information on any reduction in your PBA episodes.

### IMPORTANT SAFETY INFORMATION (continued):

#### While taking NUEDEXTA, call your doctor right away:

- If you feel faint or lose consciousness.
- If you experience lightheadedness, chills, fever, nausea, or vomiting as these may be signs of an allergic reaction to NUEDEXTA. Hepatitis has been seen in patients taking quinidine, an ingredient in NUEDEXTA.
- If you have unexplained bleeding or bruising. Quinidine, an ingredient in NUEDEXTA, can cause a reduction in the number of platelets in your blood which can be severe and, if left untreated, can be fatal.
- If you feel dizzy, since it may increase your risk of falling.
- If you have muscle twitching, confusion, high blood pressure, fever, restlessness, sweating, or shivering, as these may be signs of a potential drug interaction called serotonin syndrome.

Please see additional Important Safety Information on the following pages.



Jill is a real patient living with PBA.

# What Are the Side Effects of NUEDEXTA?

## NUEDEXTA Is Well Tolerated

**Some of the most common side effects when taking NUEDEXTA:** diarrhea, vomiting, weakness, dizziness, cough, swelling of feet and ankles.

These side effects were each seen in less than 15% of patients taking NUEDEXTA in a clinical trial. This is not a complete list of side effects. Tell your doctor about any side effects that bother you or do not go away.

### Before taking NUEDEXTA:

- Tell your doctor about all medications and supplements you are taking.
- Ask your doctor what medications you cannot use with NUEDEXTA.
- Tell your doctor if you have heart disease, or if you or a family member have ever had any heart rhythm problems.

### IMPORTANT SAFETY INFORMATION (continued):

**The most common side effects of NUEDEXTA include:** diarrhea, dizziness, cough, vomiting, weakness, and swelling of feet and ankles. This is not a complete list of side effects. Tell your doctor about any side effect that bothers you or does not go away.

**Please see additional Important Safety Information on the following pages.**

# How Do I Track My Progress?

**Write down the changes you see during treatment, such as the frequency and severity of your symptoms, to share with your doctor at your next visit. Be sure to take note of any questions or concerns you may have to discuss at your next visit.**

## Are You Seeing Results?

**Keeping track of the differences you see during treatment with NUEDEXTA** will help you remember what changes you've noticed in comparison to life before treatment. This can help your doctor understand how NUEDEXTA is working for you.

**How many PBA episodes** are you having each day? Write them down in the Episode Tracker on the next page.

**What differences have you seen in your daily routine** due to a change in PBA episodes? Even small changes are important to track.

**Share these notes with your doctor.**

# Episode Tracker

Write down the number of PBA episodes you have each day through your first 90 days of treatment.

I started taking NUEDEXTA on this day: \_\_\_\_\_ (MM/DD/YYYY)

**DAY 1-30**

**DAY 31-60**

**DAY 61-90**



Jill (right) is a real patient living with PBA. The other person depicted is not a real patient.

# The Importance of Staying on Treatment

Don't stop taking NUEDEXTA without talking to your doctor. Even if you start to feel better, it's important to keep taking NUEDEXTA as prescribed. It may take time to feel the effect of NUEDEXTA, so don't change your routine or stop taking NUEDEXTA without talking to your doctor first.

Throughout the course of your treatment, your doctor may want to determine if you still need to take NUEDEXTA. For some patients, PBA symptoms may improve on their own.

## Treatment Support

NUEDEXTA is available at most retail pharmacies. Your insurance provider and plan often determine where your prescription gets filled and your cost. When filling your prescription:

- Confirm with your provider's office where your NUEDEXTA prescription was sent and note the pharmacy's name and phone number.
- Look out for communications from the pharmacy and respond promptly to confirm important details and payment information, and to arrange pickup or delivery.
  - The pharmacy may try to reach you from a number you don't recognize.
  - If you have a NUEDEXTA Co-Pay Savings Card, make sure to share your card information with the pharmacy.

The time the process takes may vary. Some prescriptions are filled immediately, while others may take a bit longer if a prior authorization\* is required. However, if you haven't received your medication as expected, follow up with your doctor and the pharmacy where your prescription was sent.

\*Prior authorization is an approval of coverage from your insurance company (not your doctor). The process is intended to ensure that certain medications are appropriate and cost-effective for your treatment. If a prior authorization is denied, you and/or your doctor may be able to appeal the decision.

# Save on Your NUEDEXTA Prescription

NUEDEXTA is covered by most insurances, including Medicare and Medicaid. However, there are options that may help make your out-of-pocket costs more affordable. Some insurance providers and Medicare Part D plans may require prior authorization.

## NUEDEXTA Co-Pay Savings Card

If you have private insurance, the NUEDEXTA Co-Pay Savings Card may help you save on your prescription and refills.

With the **NUEDEXTA Co-Pay Savings Card**, eligible patients pay as little as:



**Scan the QR code  
to download the  
Co-Pay Savings Card.**

\*Restrictions apply. Eligible patients may pay as little as \$0 for a 90-day supply of NUEDEXTA® or \$20 for a 30-day supply of NUEDEXTA® with a maximum savings of \$1,335 per use and an annual maximum savings of \$2,670 per calendar year. Benefit cap applies regardless of co-pay amount.

## NUEDEXTA Connect Can Help

NUEDEXTA Connect is designed to help appropriately navigate the complexities of coverage for patients prescribed NUEDEXTA.

### Call for support services

**1-855-468-3339**

Monday - Friday, 8 a.m. - 8 p.m. Eastern time.



**Learn more from  
Otsuka Patient Support.**

## PBA Talk

### Connect with a PBA Ambassador

The PBA Ambassadors are real patients and caregivers living with PBA. Read their stories, watch testimonial videos about their PBA journeys, and connect with a community of people who understand what it's like living with or caring for someone with PBA.

Visit [NUEDEXTA.com/real-stories](https://www.nuedexta.com/real-stories) to learn more.

## IMPORTANT SAFETY INFORMATION (continued):

You are encouraged to report side effects of NUEDEXTA® (dextromethorphan HBr and quinidine sulfate). Please contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 ([www.fda.gov/medwatch](https://www.fda.gov/medwatch)).

**Please see additional Important Safety Information on the following pages.**



Want to learn more about  
NUEDEXTA? Scan the QR code to  
learn more or visit [NUEDEXTA.com](https://www.nuedexta.com)

### Contact Us

For more information about PBA and treatment with the first and only  
FDA-approved treatment for PBA, NUEDEXTA, call 1-855-468-3339.

**Please see the following Brief Summary of Important Facts.**

### INDICATION:

NUEDEXTA is approved for the treatment of Pseudobulbar Affect (PBA).

PBA is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury. PBA episodes are typically exaggerated or don't match how the person feels. PBA is distinct and different from other types of emotional changes caused by neurologic disease or injury. NUEDEXTA is only available by prescription.

**Please read the Brief Summary of Important Facts on the following page.**

# IMPORTANT FACTS

(Pronounced: new-DEX-tuh)

## NUEDEXTA®

(dextromethorphan HBr and 20 mg quinidine sulfate) capsules 10 mg

### ABOUT NUEDEXTA

- NUEDEXTA® is approved for the treatment of Pseudobulbar Affect (PBA). PBA is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury. PBA episodes are typically exaggerated or don't match how the person feels. PBA is distinct and different from other types of emotional changes caused by neurologic disease or injury.
- NUEDEXTA is only available by prescription.

### DO NOT TAKE NUEDEXTA IF YOU

- Are taking other drugs that contain quinidine, quinine, or mefloquine.
- Have a history of allergic reactions or intolerance (including hepatitis, low blood cell count, or lupus-like syndrome) to quinidine, quinine, or mefloquine.
- Have ever been allergic to dextromethorphan (commonly found in some cough medicines).
- Are taking, or have taken, drugs called monoamine oxidase inhibitors (MAOIs). MAOIs cannot be taken within 14 days before or after taking NUEDEXTA.
- Have had heart disease or have a family history of heart rhythm problems.
- Are taking drugs such as thioridazine and pimozide that interact with NUEDEXTA and cause changes in heart rhythm.
- If you have certain heart conditions or are taking certain medicines, your doctor may test your heart rhythm (heartbeats) before you start NUEDEXTA.

### NUEDEXTA MAY CAUSE SERIOUS SIDE EFFECTS

- Stop NUEDEXTA if these side effects occur:
  - Symptoms including lightheadedness, chills, fever, nausea, or vomiting may be a sign of an allergic reaction, or thrombocytopenia which if left untreated can be fatal.
  - Hepatitis has been seen in patients taking quinidine, an ingredient in NUEDEXTA.
  - Abnormal heart rhythm. Stop NUEDEXTA and tell your doctor immediately as it may be a sign of Torsades de Pointes.
- In some cases NUEDEXTA can interact with antidepressants causing confusion, high blood pressure, fever, restlessness, sweating, and shivering. Tell your doctor if you experience any of these side effects.
- Tell your doctor if you've ever been diagnosed with myasthenia gravis. If so, NUEDEXTA may not be right for you.

### POSSIBLE COMMON SIDE EFFECTS OF NUEDEXTA

The most common side effects in patients taking NUEDEXTA were diarrhea, dizziness, cough, vomiting, weakness and swelling of feet and ankles.

- If you are unsteady on your feet or if you have fallen before, be careful while taking NUEDEXTA to avoid falling.
- **This is not a complete list of side effects.**
- **Tell your doctor if you have any side effect that bothers you or does not go away.**

### TAKING NUEDEXTA ALONG WITH OTHER MEDICATIONS

- Tell your doctor about all medicines, supplements, and vitamins you take before starting NUEDEXTA.
- NUEDEXTA may interact with other medications causing potentially serious side-effects, and may affect the way NUEDEXTA or these other medicines work. Your doctor may adjust the dose of these medicines if used together with NUEDEXTA:
  - Antidepressants.
  - Certain heart or blood pressure medications. Your doctor may test your heart rhythm before you start NUEDEXTA.
  - Digoxin.
  - Alcohol. Limit alcohol intake while taking NUEDEXTA.
  - **These are not the only medicines that may cause problems when you take NUEDEXTA.**
- Before starting a new medicine, remind your doctor if you are taking NUEDEXTA.

### ADDITIONAL IMPORTANT INFORMATION

- **If your PBA symptoms do not improve or if they get worse, contact your healthcare provider.**
- NUEDEXTA has not been studied in patients less than age 18 or in pregnant women. Tell your doctor if you may be pregnant.
- Nursing mothers: Because many drugs are excreted in human milk, discuss with your healthcare provider if you are nursing.
- Take NUEDEXTA exactly as your doctor prescribes it.
- You and your healthcare provider should talk regularly about whether you still need treatment with NUEDEXTA.
- NUEDEXTA may be taken with or without food.
- Keep NUEDEXTA and all medicines out of reach of children.
- The need for continued treatment should be reassessed periodically, as spontaneous improvement of PBA occurs in some patients.

### NEED MORE INFORMATION?

This information about NUEDEXTA is important but is not complete. To learn more:

- Talk to your healthcare provider or pharmacist
- Visit [www.Nuedexa.com](http://www.Nuedexa.com) for FDA-approved Prescribing Information or call 1-855-4NUEDEX (1-855-468-3339).

### NEED PRESCRIPTION ASSISTANCE?

- Call 1-855-4NUEDEX (1-855-468-3339) to speak with a member of our support team for tips, tools and co-pay information.

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