



Is your loved one experiencing sudden, frequent, **UNCONTROLLABLE** episodes of **LAUGHING** and/or **CRYING** that are exaggerated or simply don't match how they feel?

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For people with certain neurologic conditions or brain injury, these could be symptoms of Pseudobulbar Affect (PBA).

**NUEDEXTA<sup>®</sup>**

(dextromethorphan HBr and  $\frac{20}{10}$  mg quinidine sulfate) capsules

Please see Important Safety Information inside and enclosed Brief Summary of Important Facts

# NUEDEXTA

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



## What is NUEDEXTA approved for?

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- NUEDEXTA is approved for the treatment of Pseudobulbar Affect (PBA). PBA is a medical condition that causes involuntary, sudden, and frequent episodes of laughing and/or crying 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.



**Because PBA episodes are unpredictable, they can leave your loved one feeling confused. But PBA is treatable.**

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As the first and only FDA-approved treatment for PBA, NUEDEXTA could make a real difference in reducing episodes.

## **What's inside:**

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## Learn about PBA.

PBA (Pseudobulbar Affect) is a separate, treatable condition that causes sudden, frequent, uncontrollable episodes of laughing and/or crying that are exaggerated or don't match how your loved one feels.

PBA affects almost

# 2 MILLION

people in the US who have certain neurologic conditions or traumatic brain injury.\*

### Some neurologic conditions PBA can follow are†:

- Traumatic Brain Injury (TBI)
- Dementia/Alzheimer's Disease
- Stroke
- Multiple Sclerosis (MS)
- Amyotrophic Lateral Sclerosis (ALS)
- Parkinson's Disease

\*Work SS, Colamonico JA, Bradley WG, Kaye RE. Pseudobulbar affect: an under-recognized and under-treated neurological disorder. *Adv Ther.* 2011;28(7):586-601.

† This is not a complete list. Other neurologic conditions have also been associated with PBA.

## 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.

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**PBA is sometimes overlooked or mistaken for depression. While it is possible to have both, they should be diagnosed and treated on their own.**

With PBA, laughing and/or crying episodes are uncontrollable.

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With depression, crying can be voluntarily controlled or managed.

With PBA, laughing and/or crying is exaggerated to the mood or doesn't match feelings.

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With depression, outward expressions match feelings.

With PBA, laughing and/or crying may last seconds to minutes.

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With depression, symptoms may last weeks to months.

If your loved one is experiencing PBA symptoms, treatment could make a real difference in reducing episodes. **To help determine if your loved one may have PBA, answer the questions on page 9 and give it to the nurse, doctor, or social worker who cares for them.**

## **IMPORTANT SAFETY INFORMATION (Continued)**

- 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 NUDEXTA and certain other medicines can interact causing side effects.

## Discover NUEDEXTA. The first and only FDA-approved treatment for PBA.

After the first week of a 12-week trial, the average reduction in PBA (Pseudobulbar Affect) episodes for patients taking NUEDEXTA was 44%.\* At the end of the trial, patients reported:

**Week 12**

**82%**

fewer episodes on average\*

**Last 2 weeks**

**51%**

were episode-free\*

Compared to baseline, patients taking placebo experienced 19% fewer PBA episodes at Week 1 and 45% fewer episodes at Week 12. In the final 2 weeks of the 12-week study, 29% of patients taking placebo were completely free of PBA episodes.\*

Results may vary.

\*Pioro EP, Brooks BR, Cummings J, et al. Dextromethorphan plus ultra low-dose quinidine reduces pseudobulbar affect. *Ann Neurol*. 2010;68(5):693-702.

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## **NUEDEXTA is well-tolerated**

### **Some of the most common side effects when taking NUEDEXTA:**

- Diarrhea
- Dizziness
- Cough
- Vomiting
- Weakness
- 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 loved one's doctor about any side effects that bother them or do not go away.

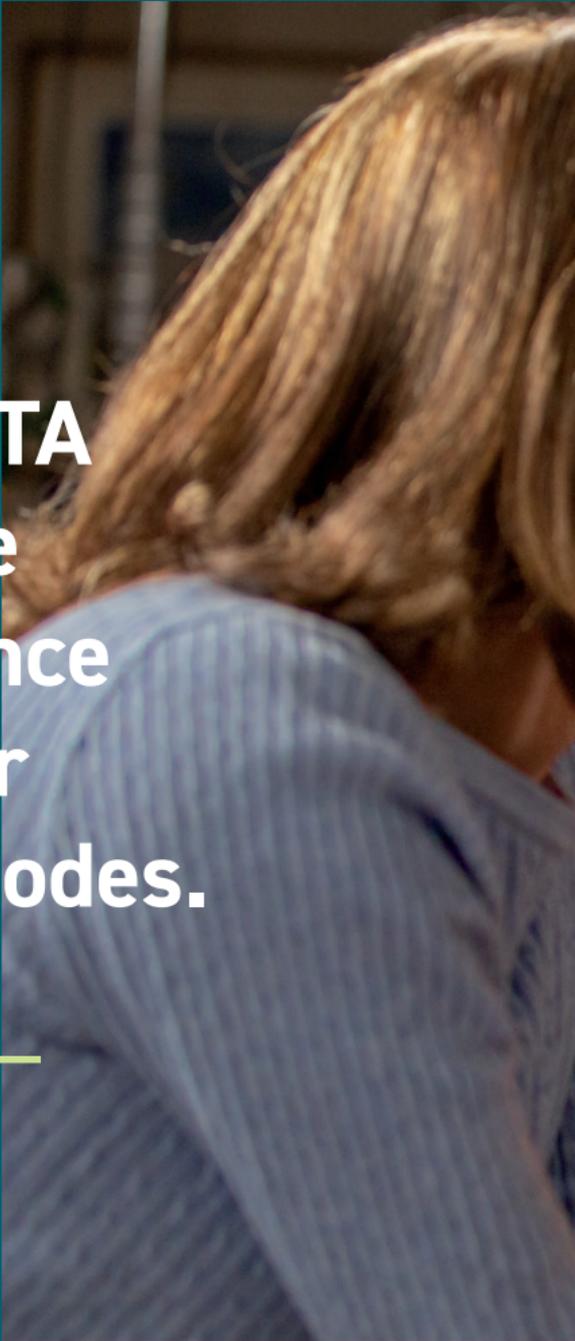
## **IMPORTANT SAFETY INFORMATION (Continued)**

### **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.

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**NUEDEXTA  
can make  
a difference  
with their  
PBA episodes.**

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### **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.



**Please see Important Safety Information and enclosed Brief Summary of Important Facts**

## Could your loved one have PBA? Fill out this PBA questionnaire.

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If you suspect your loved one might have PBA (Pseudobulbar Affect), use this tool to help healthcare professionals make a proper diagnosis.

Simply answer the questions and give it to the nurse, doctor, or social worker who works with your loved one. **Only a doctor can determine if your loved one has PBA.**

### Background

Name: \_\_\_\_\_

has been diagnosed with the following  
(choose all that apply):

- Traumatic Brain Injury (TBI)
- Dementia/Alzheimer's Disease
- Stroke
- Parkinson's Disease
- Amyotrophic Lateral Sclerosis (ALS)
- Multiple Sclerosis (MS)
- Other neurologic condition(s)

\_\_\_\_\_

Date of diagnosis \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

## Tell us what you've noticed

My loved one has been experiencing uncontrollable episodes of:

- Laughing**       **Crying**

Description of laughing and/or crying episode(s)

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These episodes seem to be:

- Sudden**  
 **Frequent**  
 **Uncontrollable**  
 **Exaggerated**  
 **Inconsistent with their mood**

I first noticed these episodes on

\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

I have seen these episodes for approximately

\_\_\_\_\_  days     weeks     months

They appear to be triggered by (if applicable)

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## Understand dosing for your loved one.

It's important that your loved one takes their prescribed dose every day to get the best results. Remember, NUEDEXTA can only help control PBA (Pseudobulbar Affect) episodes if the right amount is in their system. Here's how the care team will be administering the medicine:

**For week**

**ONE**



**one capsule is given  
each morning.**

This dose introduces  
NUEDEXTA to the body.

### IMPORTANT SAFETY INFORMATION (Continued)

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

- 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.

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Your loved one's care team will track and assess how well treatment is working. The doctor should periodically reassess the need for treatment as PBA symptoms may sometimes improve on their own.

**Starting week**

**TWO**



**on day eight, the dose will be increased to two capsules per day—one in the morning, one in the evening, 12 hours apart.**

This will be your loved one's daily dose for the rest of their treatment.

## **IMPORTANT SAFETY INFORMATION (Continued)**

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

- 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 potential drug interaction called serotonin syndrome.

## NUEDEXTA is meant to work over time.

Your loved one should see their best results after:

# 90 DAYS

of treatment.\*

**To continue the benefits of NUEDEXTA, your loved one should take daily as directed by their physician.**

In a clinical trial, at the beginning of the second week of treatment, patients increased their NUEDEXTA dosage to 2 capsules each day. After the clinical trial was over, many patients were monitored for another 3 months. During the transition between trials, some patients had a gap in treatment. Many of those who stopped saw their PBA symptoms increase after a 48-hour break in treatment.†

From time to time, your loved one's doctor may want to determine if they still needs to take NUEDEXTA. For some patients, PBA (Pseudobulbar Affect) symptoms may improve on their own.

\*Pioro EP, Brooks BR, Cummings J, et al. Dextromethorphan plus ultra low-dose quinidine reduces pseudobulbar affect. *Ann Neurol*. 2010;68(5):693-702.

† Patients with ALS or MS who stopped NUEDEXTA treatment after the initial 12-week trial had their final CNS-LS (Center for Neurologic Study-Lability Scale) scores compared to their scores at the beginning of a 12-week open-label extension trial. An increase in CNS-LS scores indicated a return of PBA symptoms.

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If you or your loved one has questions about PBA or NUEDEXTA:

**CALL**  
**1-855-468-3339**

**VISIT**  
**NUEDEXTA.com**

## **IMPORTANT SAFETY INFORMATION (Continued)**

**The most common side effects of NUEDEXTA** are 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.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 800-FDA-1088.

**Please see enclosed Brief Summary of Important Facts.**

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## Get savings support.

**NUEDEXTA is covered by most Medicare plans nationwide**, including Medicare Prescription Drug Plans (PDP), Medicare Advantage Plans (MA), and Special Needs Plans (SN). In fact, 78% of Medicare Part D patients pay \$15 or less for a NUEDEXTA prescription.<sup>a</sup>

<sup>a</sup> IQVIA, LAAD Dataset; January, 2018 - December, 2020; Medicare Insured; N=628k total claims



**Call**

**1-855-468-3339**

to see if you qualify for assistance.

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**NUEDEXTA Connect** is designed to help residents prescribed NUEDEXTA to appropriately navigate the complexities of the managed care landscape. By enrolling in NUEDEXTA Connect, residents receive help accessing NUEDEXTA, which may include the following support and information:

- **Benefits verification**
- **Prior authorization and formulary exception support**
- **Financial support for uninsured and underinsured patients\***
- **Helpful information about NUEDEXTA**

\*Restrictions apply. Not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). Benefit cap applies regardless of co-pay amount.

### **FOR SUPPORT SERVICES:**

Call 1-855-4NUEDEX (1-855-468-3339) Monday through Friday 8 AM to 8 PM ET.

**Please see Important Safety Information and enclosed Brief Summary of Important Facts**

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quinidine sulfate) capsules 10 mg

**As the first and only FDA-approved treatment for PBA (Pseudobulbar Affect), NUEDEXTA could make a real difference by reducing episodes.**

Read this brochure to learn how.

If you have questions about PBA or NUEDEXTA:

**CALL**

**1-855-468-3339**

**VISIT**

**NUEDEXTA.com**

For people with certain neurologic conditions or brain injury, sudden, frequent, uncontrollable laughing and/or crying that is exaggerated or doesn't match how they feel may be a sign of Pseudobulbar Affect (PBA).

Please see Important Safety Information inside and enclosed Brief Summary of Important Facts

## IMPORTANT FACTS

(Pronounced: new-DEX-tuh)

## NUEDEXTA®

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### 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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MLR-NUE-US-0993-0620 Rev. Date June 2020

