

NUEDEXTA®

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

Are you experiencing uncontrollable crying and/or laughing?

You may have **Pseudobulbar Affect (PBA).**



Actor portrayal. Not real PBA patients.

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 Important Safety Information inside and Brief Summary of Important Facts.

What Is PBA?

Pseudobulbar Affect (PBA) is a medical condition that causes **crying and/or laughing that is sudden, frequent, and uncontrollable and is exaggerated or doesn't match how you feel.**

Conditions That Can Cause PBA:

- Traumatic brain injury (TBI)
- Stroke
- Multiple sclerosis (MS)
- Alzheimer's disease and dementia
- Amyotrophic lateral sclerosis (ALS)
- Parkinson's disease

PBA Is Treatable

PBA symptoms can be:

Involuntary

"It happens in public. I can't control it."

Sudden

"I cry for no reason. It comes out of the blue."

Frequent

"I cry more than I used to. The littlest thing sets me off."

Exaggerated

"I overreact to things now. My response is excessive."

Incongruent

(not matching with how you feel)

"I don't know why I am laughing. It's not funny."

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.
- 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.

PBA Is a Neurologic Condition

PBA is a neurologic condition, not a psychiatric condition like depression, although PBA symptoms can be similar. With PBA, there is a disconnect between mood (how you feel) and expression (physical manifestation). The parts of our brain that normally control emotional responses are the cerebral cortex and the cerebellum. Damage to the cerebellum, from a neurologic condition or brain injury, may lead to miscommunication with the cerebral cortex. This miscommunication is thought to result in PBA episodes.

PBA's Impact Can Be Substantial

The impact of PBA may present a considerable burden in addition to the difficulties of living with a neurologic condition or brain injury. PBA episodes can be very frustrating for individuals experiencing them, as well as for those around them, because the episodes can be misunderstood and easily lead to confusion and embarrassment.

It's important to know that you are not alone. Many patients, including our PBA Ambassadors, have had similar experiences. Tell your doctor how PBA episodes impact you so they can help you best manage your symptoms.

PBA Is More Common Than You Think

PBA is thought to affect about **1.8 million** people in the U.S.*[†] However, PBA is underrecognized, underdiagnosed, and undertreated.

*When considering patients with any of six common neurologic conditions associated with PBA, it is estimated that 37%, or an estimated 7.1 million Americans, have symptoms suggestive of PBA as defined by a Center for Neurologic Study-Lability Scale (CNS-LS) score ≥ 13 and 9.4% of patients, or an estimated 1.8 million Americans, with CNS-LS scores ≥ 21 . The presence of PBA symptoms was defined as a CNS-LS score ≥ 13 and a more restrictive definition was also evaluated using CNS-LS ≥ 21 . The CNS-LS was validated as a PBA screening tool in ALS and MS populations. A CNS-LS score ≥ 13 merits further diagnostic assessment.

[†]Common neurologic conditions included Alzheimer's/dementia, ALS, MS, Parkinson's, stroke, and TBI.

"For me, having a PBA diagnosis and then having a treatment truly makes a difference."

Mary-Beth
Patient living with epilepsy and PBA



Please see additional Important Safety Information on the following pages.

How PBA Is Diagnosed

PBA is typically diagnosed during a neurological exam by a specialist experienced in treating neurologic conditions or brain injuries. While there is no definitive test to diagnose PBA, doctors may use the Center for Neurologic Study-Lability Scale (CNS-LS) as a part of their evaluation. They will assess the patient and provide a diagnosis based on a thorough understanding of:

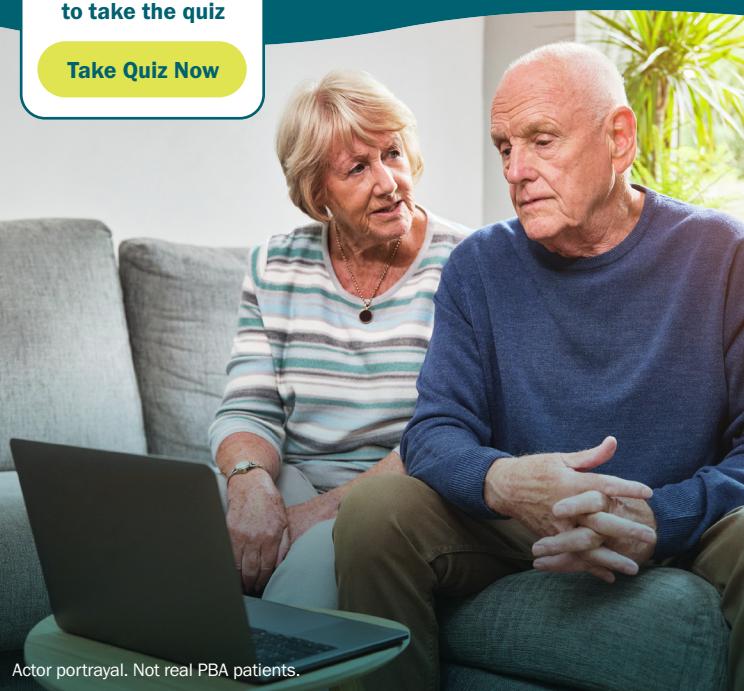
- Symptoms
- Medical history, especially the existence of a primary neurologic condition or brain injury
- Mental health history
- Findings from a physical exam

The PBA Quiz

Wondering if you may have PBA? Take a first step in learning whether your symptoms suggest PBA by taking the PBA Quiz.

Click below
to take the quiz

[Take Quiz Now](#)

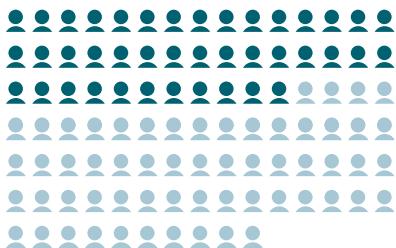


Actor portrayal. Not real PBA patients.

PBA May Be Misdiagnosed

PBA symptoms can look like a lot of other conditions, so it can be difficult to diagnose. An online survey of 637 respondents in the U.S. who reported frequency of episodes suggestive of PBA* and discussed their episodes of sudden crying and/or laughing with a doctor found that:

41%
of respondents
(N=227) were
misdiagnosed.



*A CNS-LS score ≥13 is suggestive of PBA symptoms.

PBA is frequently mistaken for depression because of the overlap with symptoms of mood disorders and other conditions.

"I was confused because [my doctor] was telling me that I had depression, and they were prescribing me antidepressants, but I was still crying uncontrollably all the time. So, I thought it had to be something else."

Sequena | A stroke survivor living with PBA



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

How PBA and Depression Are Different

Although PBA can be misdiagnosed as depression, remember that PBA and depression are separate and treatable conditions:

PBA

A secondary neurologic condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury.

Depression

A common but serious mood disorder that causes severe symptoms that affect how a person feels, thinks, and handles daily activities.

Crying in PBA

- Disproportionate to or inconsistent with how the patient feels.
- Uncontrollable.
- Happens frequently, suddenly, and may be brief or extended.

Crying in Depression

- Matches how the patient feels.
- Mostly controllable; stops when mood changes.
- Onset and duration defined by mood.

57%
of patients

It's common to have PBA alongside depression or other mood disorders. In a clinical study, **over half of patients who were diagnosed with PBA also had depression.^{*†}** That's why everything you discuss with your doctor is so important.

*PRISM II was a 90-day, open-label, single-arm, 74-site, U.S. trial in adult patients with dementia, stroke, or traumatic brain injury. All patients received a clinical diagnosis of PBA by their physician and had a (CNS-LS) score ≥13 at baseline. CNS-LS is a 7-item self-report rating scale that measures perceived frequency and control over crying and/or laughing episodes. It was validated as a PBA screening tool in amyotrophic lateral sclerosis and multiple sclerosis populations. CNS-LS ≥13 may suggest PBA but does not confer a PBA diagnosis.

[†]Based on Patient Health Questionnaire-9 (PHQ-9), a 9-item assessment of depressive symptoms. Scores range from 0 to 27, with higher scores indicating increased depression severity.

Please see additional Important Safety Information on the following pages.

Talking to Your Doctor

Since crying and laughing are normal displays of emotion, it can be challenging to try to explain how your crying and/or laughing isn't normal, especially when you're not sure why it's happening. Prepare for your doctor's appointment so you're equipped to explain your episodes and how they affect you.

Here is some important information to share with your doctor. Be as detailed as possible and relay specific instances. For example:

- Changes in your crying and/or laughing: how severe it is, how long it lasts, or how often it occurs.
- Whether your crying and/or laughing is involuntary, sudden, frequent, or uncontrollable.
- If your crying and/or laughing does or doesn't match your mood.
- How disruptive your crying and/or laughing is when it comes to work and interacting with others.

Advocate for Yourself

No one knows you better than yourself. It's OK to let your doctor know if something doesn't seem right to you.

For more information on how to prepare for a conversation with your doctor, [click to download the Doctor Discussion Guide below.](#)

[Download Now](#)

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.

PBA Is Treatable

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

NUEDEXTA contains quinidine and should not be used concomitantly with other drugs containing quinidine, quinine or mefloquine.

NUEDEXTA is proven to reduce PBA episodes

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.



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

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.

What To Expect With NUEDEXTA

You and your doctor have made the important decision to treat your PBA with NUEDEXTA. 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.

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):

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).

Please see additional Important Safety Information on the following pages.

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.

Track Your Progress

Use this treatment guide to note any changes you see during treatment, like the frequency and severity of your symptoms, to share with your doctor at your next visit.

Click below to access the PBA Treatment Guide

[Download Now](#)

NUEDEXTA Is Well Tolerated

Some of the most common side effects when taking NUEDEXTA are: 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.

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 see additional Important Safety Information on the previous pages.

Treatment Support

NUEDEXTA is covered by most insurances, including Medicare and Medicaid.

Medicare: NUEDEXTA is covered by Medicare Plans nationwide, including Medicare Prescription Drug Plans (PDP), Medicare Advantage Plans (MA), and Special Needs Plans (SN). Some insurance providers and Medicare Part D plans may require prior authorization.*

Commercial Insurance: If you have commercial insurance, 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.
- 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).

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

Click below to learn more from
Otsuka Patient Support

[Learn More](#)

Please see additional Important Safety Information on the previous pages.

Save on Your NUDEXTA Prescription

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

Make sure to share your card with the pharmacy.

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

\$0*

for a **90-day** prescription

\$20

for a **30-day** prescription

*Restrictions apply. Eligible patients may pay as little as \$0 for a 90-day supply of NUDEXTA® or \$20 for a 30-day supply of NUDEXTA® 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.

Click to download the Co-Pay Savings Card

Download Now

Want to learn more about NUDEXTA? Click below.

NUDEXTA.com

Please see the attached Brief Summary of Important Facts.

NUDEXTA®

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



Otsuka America Pharmaceutical, Inc.

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IMPORTANT FACTS

(Pronounced: new-DEX-tuh)

NUEDEXTA®

(dextromethorphan HBr and
quinidine sulfate) capsules 20 mg
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.Nuedexta.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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Otsuka America Pharmaceutical, Inc.