Understand PBA

PBA (PseudoBulbar Affect) is a separate, treatable condition that causes sudden, frequent, uncontrollable episodes of crying and/or laughing that are exaggerated or don’t match how you feel.

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)
- Alzheimer’s disease/dementia
- Stroke
- Multiple sclerosis (MS)
- ALS (Lou Gehrig’s disease)
- Parkinson’s disease

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

To start saving, follow these steps:
1. Visit NUEDEXTA.com/activate or call 1-855-468-3339
2. Show your Co-Pay Savings Card to the pharmacist

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, these could be symptoms of PseudoBulbar Affect (PBA).

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.
Because PBA episodes are unpredictable, they can leave you feeling misunderstood. But PBA is treatable.

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

What is NUEDEXTA approved for?

- 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.

What’s inside:

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5 Learn about NUEDEXTA
9 Take the PBA Quiz
11 Have the PBA conversation
15 Follow your dosing routine
21 Get savings support
23 Activate your Savings Card
Understand PBA

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

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, crying and/or laughing episodes are uncontrollable.
With depression, crying can be voluntarily controlled or managed.
With PBA, crying and/or laughing is exaggerated or doesn't match feelings.
With depression, outward expressions match feelings.
With PBA, crying and/or laughing may last seconds to minutes.
With depression, symptoms may last weeks to months.

If you’re experiencing PBA symptoms, treatment could make a real difference in reducing your episodes. Take the quiz, starting on page 9, to help your doctor determine if you have PBA.

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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.

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 NUEDEXTA and certain other medicines can interact causing side effects.
Learn about NUEDEXTA

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 and 29% were completely free of PBA episodes in the final 2 weeks of the 12-week study.*

Your results may vary.


NUDEXTA 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 doctor about any side effects that bother you 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.
“I can have a day with my dad and worry less about a crying outburst in public.”

Caregiver for Alzheimer’s patient living with PBA (PseudoBulbar Affect) and taking NUEDEXTA

Please see Important Safety Information and enclosed Brief Summary of Important Facts
Take the PBA Quiz

Once you’ve taken the quiz, use your results and the PBA Conversation Guide, starting on page 11, to help your doctor understand the daily impact PBA (PseudoBulbar Affect) has on your life.

For each item, use this scale to write the number that applies to you or your loved one during the past week.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>Rarely</td>
<td>Occasionally</td>
<td>Frequently</td>
<td>Most of the time</td>
</tr>
</tbody>
</table>

4 I find that even when I try to control my laughter, I am often unable to do so.

5 There are times when I won’t be thinking of anything happy or funny at all, but then I’ll suddenly be overcome by funny or happy thoughts.

6 I find that even when I try to control my crying, I am often unable to do so.

7 I find that I am easily overcome by laughter.

ADD YOUR TOTAL SCORE: ____

In studies, scores of 13 or higher were more likely to suggest PBA*. However, this score can occur in persons with and without PBA. Only a doctor can determine if you have PBA.

* The Center for Neurologic Study-Lability Scale (CNS-LS) was developed by healthcare professionals to identify and measure symptoms suggestive of PBA. It does not diagnose PBA and is not intended to substitute for professional medical assessment and/or advice. Please consult with your doctor. The CNS-LS has been validated in MS and ALS patients.
Have the PBA conversation

Use the TWO QUESTIONS and follow-up ideas on the following page during your next appointment. If your doctor diagnoses you with PBA (PseudoBulbar Affect), ask if NUEDEXTA could be right for you.

If you’re a caregiver, you can use the PBA Conversation Guide to help your loved one talk to their doctor as well.

Remember, you are your best advocate. When you talk about how your symptoms are bothering you, be specific and don’t hold back—the more details you can provide, the easier it will be for your doctor to understand how PBA is affecting you.

If you need to, visit NUEDEXTA.com to take the quiz again.

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.

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.
"I felt like I couldn’t control my crying and I wanted to know what was going on.”

Post-stroke patient living with PBA (PseudoBulbar Affect), taking NUEDEXTA

Please see Important Safety Information and enclosed Brief Summary of Important Facts
Follow your dosing routine

It’s important that you take your prescribed dose every day to get the best results. Remember, NUEDEXTA can only help control your PBA (PseudoBulbar Affect) episodes if the right amount is in your system.

For week ONE

take one capsule each morning.

This dose introduces NUEDEXTA to your body.

Starting week TWO

on day eight, increase your dose to two capsules per day—one in the morning, one in the evening, 12 hours apart.

This will be your daily dose for the rest of your 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.

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.
Follow your dosing routine

Because NUEDEXTA is meant to work over time, you should:

See your best results after 90 DAYS of treatment.*

To continue the benefits of NUEDEXTA, take daily as directed by your 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 doctor may want to determine if you still need to take NUEDEXTA. For some patients, PBA (PseudoBulbar Affect) symptoms may improve on their own.

If you miss a dose, follow these instructions below:

- Do not take a double dose
- Take the next dose of NUEDEXTA at the usual time
- Do not take more than 2 capsules in a 24-hour period

If you have 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 or call 800-FDA-1088.

†Patients with ALS or MS who stopped NUEDEXTA treatment after the initial 12-week trial had their final CNS-LS 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.
“Since NUEDEXTA I am less worried about having an episode.”

Post-traumatic brain injury patient living with PBA (PseudoBulbar Affect), taking NUEDEXTA

Please see Important Safety Information and enclosed Brief Summary of Important Facts
Get savings support

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

However, regardless of your situation, there are options to help make your out-of-pocket costs more affordable.

Visit NUEDEXTA.com to sign up for savings and helpful information about your treatment.

Call 1-855-468-3339
to see if you qualify for assistance.

If you have government insurance (Medicare, Medicaid, etc.), Advanced Patient Services may be able to help.

If you are uninsured, underinsured, or cannot afford your medication, financial assistance may be available. Restrictions apply.

If you have private insurance, turn to the next page to learn how our Co-Pay Savings Card can help you save.

Please see Important Safety Information and enclosed Brief Summary of Important Facts
Activate your Savings Card

With your Co-Pay Savings Card, you can save on your NUEDEXTA 90-day prescription, including refills.

Most privately insured patients

Pay as little as

$0*
for a 90-day prescription

or $30* for a 30-day prescription.

Over 76%† of patients with insurance pay $30 or less per month.

To start saving, follow these steps:

1. Visit NUEDEXTA.com/activate or call 1-855-468-3339
2. Show your Co-Pay Savings Card to the pharmacist

*Restrictions apply. Benefit cap applies regardless of copay amount. Those eligible for Medicare, Medicaid, or any other government healthcare program are not eligible for this program.

†Symphony Health Dynamic Claims Data 2016.

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Important Safety Information

Before you take NUDEXTA, tell your doctor:

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

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2. Show your Co-Pay Savings Card to the pharmacist

If you have questions about PBA or NUDEXTA:

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1-855-468-3339

VISIT
NUDEXTA.com

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

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

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

For people with certain neurologic conditions or brain injury, sudden, frequent, uncontrollable crying and/or laughing 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

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IMPORTANT FACTS

(Pronounced: new-DEX-tuh)

ABOUT NUDEXTA

• NUDEXTA® 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.

• NUDEXTA is only available by prescription.

DO NOT TAKE NUDEXTA 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 NUDEXTA.

• Have had heart disease or have a family history of heart rhythm problems.

• Are taking drugs such as thioridazine and pimozide that interact with NUDEXTA 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 NUDEXTA.

NUDEXTA MAY CAUSE SERIOUS SIDE EFFECTS

• Stop NUDEXTA 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 NUDEXTA.

  ◆ Abnormal heart rhythm. Stop NUDEXTA and tell your doctor immediately as it may be a sign of Torsades de Pointes.

• In some cases NUDEXTA 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, NUDEXTA may not be right for you.

POSSIBLE COMMON SIDE EFFECTS OF NUDEXTA

The most common side effects in patients taking NUDEXTA 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 NUDEXTA 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 NUDEXTA ALONG WITH OTHER MEDICATIONS

• Tell your doctor about all medicines, supplements, and vitamins you take before starting NUDEXTA.

• NUDEXTA may interact with other medications causing potentially serious side-effects, and may affect the way NUDEXTA or these other medicines work. Your doctor may adjust the dose of these medicines if used together with NUDEXTA:

  ◆ Antidepressants.

  ◆ Certain heart or blood pressure medications. Your doctor may test your heart rhythm before you start NUDEXTA.

  ◆ Digoxin.

  ◆ Alcohol. Limit alcohol intake while taking NUDEXTA.

  ◆ These are not the only medicines that may cause problems when you take NUDEXTA.

• Before starting a new medicine, remind your doctor if you are taking NUDEXTA.

ADDITIONAL IMPORTANT INFORMATION

• If your PBA symptoms do not improve or if they get worse, contact your healthcare provider.

• NUDEXTA 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 NUDEXTA exactly as your doctor prescribes it.

• You and your healthcare provider should talk regularly about whether you still need treatment with NUDEXTA.

• NUDEXTA may be taken with or without food.

• Keep NUDEXTA 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 NUDEXTA is important but is not complete. To learn more:

• Talk to your healthcare provider or pharmacist


NEED PRESCRIPTION ASSISTANCE?

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

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