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

Living with the Symptoms of Pseudobulbar Affect (PBA)

Onscreen Text: Living with the Symptoms of Pseudobulbar Affect (PBA)

Patient images reflect their health status at the time the video was taken. The following are real patients and caregivers who have been compensated by Otsuka America Pharmaceutical, Inc., for their time.

PBA is a neurologic condition that causes uncontrollable crying and/or laughing episodes.

It can happen in people living with certain neurologic conditions or brain injury, such as: Traumatic Brain Injury (TBI), Stroke, Multiple Sclerosis (MS), Alzheimer's disease or dementia, Parkinson's disease, Amyotrophic Lateral Sclerosis (ALS)

The impact of PBA can be substantial. PBA may affect personal relationships, work, and social activities.

NUEDEXTA® (dextromethorphan HBr and quinidine sulfate) is approved for the treatment of PBA and is proven to reduce PBA episodes. NUEDEXTA is not approved to treat the impact of PBA.

Onscreen Text:
Carol
Living with PBA

Carol: I was told that if I couldn't control my crying at school then I would no longer be able to work as a librarian it was a very painful, difficult time. And on top of all this I didn't feel sad. <laughs> I- I knew I was healing from an injury but I felt like this did not reflect who I was.

Onscreen Text:
Sequena
Living with PBA

Sequena: My kids seeing uhm... me have a PBA episode it hurt, it hurt I would try to hide it as much as possible and go- go in my room, take a breather until it passed not knowing how long it would take for them to pass, you know, sometimes it could be a minute, three minutes, four minutes, five minutes.

Onscreen Text:
Liyah
Caregiver for her mother Sequena

Liyah: Originally before the PBA was like late elementary school for me and my mom had always been the type to like, sign up for every field day, sign up for every PTA meeting, everything like that. And so it was suddenly like a drop off, like, she was not there. And so when she was having those PBA symptoms, I was just like, there is something not right, because if my mom could she would be there for me. There is no reason that she wouldn't. So I knew that there had to be something extremely wrong.

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Carol: What it's like to live with PBA, it's-- frankly, it's embarrassing. You know that you're fine inside. You know you're not having uh... a tantrum or you're faking or you're attention seeking. You know that it's real. And I wish people knew that it was, you know, a real condition that's treatable.

Onscreen Text:
For your patients with **PBA**
NUEDEXTA CAN MAKE A DIFFERENCE

NUEDEXTA provided significant reduction in PBA episodes.

Adverse events were generally mild to moderate.

NUEDEXTA has broad insurance coverage and copay savings for eligible patients.

Onscreen Text and Narrator:

INDICATION and IMPORTANT SAFETY INFORMATION for NUEDEXTA® (dextromethorphan HBr and quinidine sulfate)

INDICATION:
NUEDEXTA is indicated for the treatment of pseudobulbar affect (PBA).

PBA occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurologic disease or injury.

IMPORTANT SAFETY INFORMATION:

CONTRAINDICATIONS:

- **Quinidine and Related Drugs:** NUEDEXTA contains quinidine and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine.
- **Hypersensitivity:** NUEDEXTA is contraindicated in patients with a history of NUEDEXTA-, quinine-, mefloquine-, or quinidine-induced thrombocytopenia, hepatitis, bone-marrow depression, lupus-like syndrome, or known hypersensitivity to dextromethorphan (e.g., rash, hives).
- **MAOIs:** NUEDEXTA is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs), or in patients who have taken MAOIs within the preceding 14 days, due to the risk of serious and possibly fatal drug interactions, including serotonin syndrome. Allow at least 14 days after stopping NUEDEXTA before starting an MAOI.
- **Cardiovascular:** NUEDEXTA is contraindicated in patients with a prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, heart failure, patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide), patients with complete atrioventricular (AV) block without implanted pacemaker, or at high risk of complete AV block.

Thrombocytopenia and Other Hypersensitivity Reactions: Quinidine can cause immune-mediated thrombocytopenia that can be severe or fatal. Non-specific symptoms, such as lightheadedness, chills, fever, nausea, and vomiting, can precede or occur with thrombocytopenia. NUEDEXTA should be discontinued immediately if thrombocytopenia occurs.

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Hepatotoxicity: Hepatitis, including granulomatous hepatitis, has been reported in patients receiving quinidine, generally during the first few weeks of therapy. Discontinue immediately if this occurs.

Cardiac Effects: NUEDEXTA causes dose-dependent QTc prolongation. QT prolongation can cause torsades de pointes–type ventricular tachycardia, with the risk increasing as the degree of prolongation increases. When initiating NUEDEXTA in patients at risk for QT prolongation and torsades de pointes, electrocardiographic (ECG) evaluation of QT interval should be conducted at baseline and 3 to 4 hours after the first dose. Some risk factors include use with CYP3A4 inhibitors or drugs that prolong QT interval, electrolyte abnormalities, bradycardia, or left ventricular hypertrophy or dysfunction. If patients taking NUEDEXTA experience symptoms that could indicate the occurrence of cardiac arrhythmias (e.g., syncope or palpitations), NUEDEXTA should be discontinued, and the patient further evaluated.

Concomitant Use of CYP2D6 Substrates: NUEDEXTA inhibits CYP2D6 and may interact with other drugs metabolized by CYP2D6. Adjust dose of CYP2D6 substrates as needed.

Dizziness: NUEDEXTA may cause dizziness. Take precautions to reduce the risk of falls.

Serotonin Syndrome: Use of NUEDEXTA with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants increases the risk of "serotonin syndrome."

Anticholinergic Effects of Quinidine: Monitor for worsening in myasthenia gravis.

Adverse Reactions: The most common adverse reactions (incidence of ≥3% and two-fold greater than placebo) in patients taking NUEDEXTA are diarrhea, dizziness, cough, vomiting, asthenia, peripheral edema, urinary tract infection, influenza, increased gamma-glutamyltransferase, and flatulence.

These are not all the risks for use of NUEDEXTA.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please see **FULL PRESCRIBING INFORMATION** at nuedextahcp.com

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[NUEDEXTA logo]

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July 2024 18US24EBP0032

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