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

## Getting Diagnosed with Pseudobulbar Affect (PBA)

**Onscreen Text:**
Patients may not know how to talk about **PBA**

Posing a question about their behavior can help assess for PBA

"Do you ever cry or laugh but it feels odd because you're not actually sad or amused?"

**Onscreen Text:**
Jill
Living with PBA

**Jill:** I started seeing a new psychiatric nurse practitioner, and I was determined to discover why I was having these issues. So she started asking questions about-- just outta-the-box questions more. She asked me if I'd ever sustained a head injury, a serious one. If I had ever had laughing episodes or crying episodes that weren't connected or weren't matching the emotions I was feeling.

**Onscreen Text:**
Mary Beth
Living with PBA

**Mary Beth:** My neurologist when she told me it was PBA uh... I just I think she could read the sigh of relief on my face. Finally after all this time I <crying> I'm not lying, I'm not making it up, I'm not exaggerating, I'm just, you know, struggling with the condition that I don't have control over and uhm... it- it was just uh... like a light, you know, now it was real.

**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).

Otsuka
Otsuka America Pharmaceutical, Inc.


August 2024 18US24EBP0038

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.

**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."



August 2024 18US24EBP0038

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

**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

**Onscreen Text:**
[NUEDEXTA logo]

**Onscreen Text:**

July 2024 18US24EBP0034