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

NUEDEXTA Patient Testimonial: Carol

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Carol: Hi, my name is Carol and I have Pseudobulbar Affect as a result of a traumatic brain injury. I am a high school librarian; so, I get this huge fire safe because we have all the old yearbooks going back to 1930 – it's so big I was actually inside of the safe and I backed out and it had a low door and I whacked my head so hard and the crying started after my injury.

Onscreen Text: Carol, Diagnosed PBA Sufferer // NUEDEXTA® Patient

Onscreen Text: Carol Diaries, Living with PBA

Carol: Uncontrollable crying is – it's – a difficult to explain how draining that can be.

Onscreen Text: Carol Diaries, Living with PBA

Carol: I was sent to therapies, like occupational therapy, and they asked me to come back when I could stop crying because I couldn't get through a session. Another doctor sent me back to work. Imagine teaching a class and you are so worried that you are going to cry in front of 30 teenagers – the stress from not knowing when an episode would come on.

Tim: When the brain injury happened, all she wanted to do was avoid people. "Let me be."

Onscreen Text: Tim, Carol's Husband // Caregiver

Carol: My husband and I would be in the supermarket and I'd have to run for the car. And, one time we're in the diner and I ran out crying.

Tim: Carol and I would go to this New Year's Eve party, every year, but after she had her traumatic brain injury and she was continuously crying, she wouldn't feel like going out.

Onscreen Text: Tim Diaries, The Impact of PBA

Carol: You don't want to be in public having these episodes because it's embarrassing and it was – it was – a very difficult time.

Carol: There were a lot of unknowns through this journey for me. Each month I would get so excited

to go to the doctor and like they were going to finally have answers and the only answer was, *"you know, you'll feel better soon," "you'll feel better soon,"* but the crying wasn't subsiding.

Onscreen Text: Carol Diaries, Journey to PBA Diagnosis

Carol: I saw a neuropsychiatrist who put me on a series of anti-depression medicines but I couldn't stop crying and I was crying and crying uncontrollably and I couldn't figure it out. Now you can see where the confusion gets in with having depression – I just couldn't control why I was crying.

Carol: I just started to feel people started to doubt me, not take me seriously, maybe even thought I was faking it – nobody would ever choose to live like this.

Onscreen Text: Carol Diaries, Living with PBA

Carol: About that time, my sister who is a nurse – and she's married to a doctor – and they have a friend who is a neurologist, and she got me in to see him. He evaluated all the medications that I was currently taking; after spending time with me and listening to my symptoms, he examined me and then he diagnosed me with Pseudobulbar Affect and said that there is medication for this called NUEDEXTA. He wanted me to be fully aware that there were side effects including diarrhea, dizziness, cough, vomiting, weariness and ankle swelling. Since I've been on NUEDEXTA, I have fewer episodes; there's less fear that I'm going to – you know – embarrass myself at dinner with friends or that I won't be able to do something.

Tim: Because of the less frequent episodes, we're now more comfortable going out to dinner, going to see more movies, playing more golf.

Carol: Because of the lessening of the crying, I just have a certain comfort level.

Carol: I would say to anybody that thinks that they could potentially have PBA is to not give up hope. If your symptoms are not matching how you feel inside, it's time to take the next step; keep doing the research, keep talking to your doctor, don't give up. There is hope.

Onscreen Text: Carol Diaries, Don't Give Up

End Card:
NUEDEXTA Logo
Carol and Tim were compensated for their participation.
Visit NUEDEXTAHCP.com
THE ONLY FDA APPROVED TREATMENT PROVEN TO REDUCE PBA EPISODES.

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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.

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.

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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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