

Treating and Managing Pseudobulbar Affect (PBA)

Onscreen Text:

NUEDEXTA is the only FDA-approved treatment proven to reduce PBA episodes

Onscreen Text:

Mary Beth

Living with PBA

Mary Beth: There was a time where I went by where I was-- had been working and I had to, you know, pick up some things and I ran into somebody I normally would have probably started to cry given what had transpired before and having had episodes in front of this person before and I didn't. And so that felt like, "Oh, this is good. This time I didn't cry."

Onscreen Text:

Carol

Living with PBA

Carol: After starting the NUEDEXTA medication, it was early summer and a neighbor had a cookout and it was the-- really the first social thing I had gone to and I was a little nervous it made me feel so good to see people, to talk to people, and then-- we didn't stay long, maybe an hour, and I was walking home with my husband and it clicked, like "Oh, my gosh, like I was in a social situation and I did not have uh... a crying episode," and it felt great.

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.

NUEDEXTA®

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

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."



Otsuka
Otsuka America Pharmaceutical, Inc.

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:

© 2024 Otsuka America Pharmaceutical, Inc. All rights reserved. NUEDEXTA® is a registered trademark of Avanir Pharmaceuticals, Inc. and used under license by Otsuka America Pharmaceutical, Inc.

July 2024 18US24EBP0035



Otsuka

Otsuka America Pharmaceutical, Inc.