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

Prevalence of PBA in Your Practice: Dr. Fisher

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Dr. Fisher: Patients are often aware there is something wrong, and they will communicate in their own language that there is something wrong. Parkinson's patients overwhelmingly tell me that they're weak. There is no weakness in Parkinson's, but their description of their difficulty with movement, their slow movements, their difficulty to get up, their explanation is "weak."

Very often, patients and their caregivers who observe this emotional lability - inability to control their emotions, inappropriate laughing and crying - they would tell you what they believe is happening which is overwhelmingly with anxiety or depression. So how many times have I heard, "My mom is depressed." "My wife is depressed." "I am very anxious." And if you are in a rush, we all are, you basically say, "Oh, you are anxious, well there's no problem. Here's a medication for anxiety." And the patient says, "I am depressed." "Of course, you are depressed, you have Parkinson's, but I have something for you and here is medication for depression."

The same way when patients tell me that they are dizzy, I would never be satisfied. I said, "What do you mean by being dizzy?" The same when somebody tells me that they are depressed or anxious, I'm never satisfied. I said, "What do you mean when you say you anxious. If you mean that you cry for no reason, that may not be anxiety."

Depression is probably the most common misdiagnosis for the symptoms of PBA, therefore the key is to dig in. I never take it at face value. I say, "What do you mean by the symptoms?" Having a CNS LS of 13 or more helps me to dig a little deeper into it. That's a start of the conversation and that's why you have to screen everyone, not only people you suspect, because if you already suspect there is no reason for screening. Now just ask the question and delve in. It is people you do not suspect of having that you need to screen. Therefore, everybody in neurological practice needs to be screened.

End Slate: Otsuka America Pharmaceutical, Inc.

Onscreen text: Stanley Fisher, MD, was a paid consultant for their participation.

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

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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.

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

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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**.

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