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

TBI Patient with PBA

Onscreen Text: 43-year-old female, mother of two, former school teacher

Patient on NUEDEXTA® (dextromethorphan hydrobromide and quinidine sulfate) 20 mg/10 mg capsules

NUEDEXTA is approved for the treatment of Pseudobulbar Affect (PBA), which is involuntary crying and/or laughing that may occur in people with certain neurologic conditions. NUEDEXTA is not approved to treat other emotional symptoms.

6 minutes 45 seconds

Onscreen Text: Information presented here represents a specific case and individual results may vary.

Interviewer: So, we added the NUEDEXTA a little over two weeks ago. Can you tell me, what do you think the effects have been?

Patient: I won't cry at a family party that was really emotional to me.

Interviewer: So, you went to a family party?

Patient: My cousin's engagement.

Interviewer: And you've been to engagement parties before where you definitely would have cried, is that it?

Patient: I pretty much cry walking in, so yeah.

Interviewer: So, are there any triggers now that can get you to cry in the last couple weeks?

Patient: No, so far not. I'm really doing good.

Interviewer: Have you gone to any of the kid's games recently, because that was an issue for you.

Patient: Oh yeah, this week I had three straight.

Interviewer: So, you haven't had any outbursts?

Patient: Not a one, not zero.

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Interviewer: How may episodes of, you know, laughing or crying were occurring every day or every week prior to the treatment? On average would you say in a typical day.

Patient: At least 3-4 times a week.

Interviewer: A week, and now?

Patient: None, not a one.

Interviewer: How soon did you notice an effect from the medication?

Patient: Within the first two weeks. I can't even believe it's me, that I can even talk about it and not lose it.

INDICATION AND USAGE

NUEDEXTA® (dextromethorphan HBr and quinidine sulfate) is indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of otherwise unrelated neurological 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 neurological 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 (eg, 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 (eg, thioridazine and pimozide), patients with complete atrioventricular (AV) block without implanted pacemaker, or at high risk of complete AV block.

WARNINGS AND PRECAUTIONS

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 (eg, 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.

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Please see Full Prescribing Information at https://www.nuedextahcp.com.

End Slate:

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Actual patient testimony may not reflect general experience.

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