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

NUEDEXTA Patient Testimonial: Robert

Onscreen Text: Robert, Diagnosed PBA sufferer // NUEDEXTA® Patient

Robert: My name is Robert and I suffered from a traumatic brain injury, and I've been diagnosed with PBA, Pseudobulbar Affect, which means I have uncontrollable crying episodes.

It would be difficult to get my mind on something else so that I could try to control the crying, but with PBA, you can't control the crying.

Back in 1989, I was a paratrooper in the Army. On a night jump, the paratrooper in front of me hesitated and the static line caught my neck. My rucksack went up, hit my head and the next thing I knew, there was a chopper coming to pick me up and take me to the emergency room and the crying episodes happened every day, and this went on for weeks, months, even years.

It was challenging because before I was a boy who'd became a man and wanted to serve my country. I wasn't sad. I wasn't hurt. It's a passion to do your job properly, protect and defend, and then the tears would come and made it difficult for the person witnessing that and then having' to explain – you know – or get around it or hide it was challenging.

I had conversations with the doctors, and we were just having difficulties trying to manage it. The term depression came up consistently, but I wasn't feeling' sad; I didn't feel depressed. I was prescribed medicine for it; I took it, but the crying episodes kept happening.

Robert: Life was challenging because I always felt an episode of uncontrollable crying was going to happen, and to deal with that, socially was difficult.

Onscreen Text: Robert Diaries, Living with PBA

Robert: To cope, I would figure out an exit – running to the bathroom, leaving a meeting, leaving a social gathering, going to my car – it was just a matter of where I could hide to try to gain control of myself and of the crying episode that was about to manifest.

Well, I realized it during the television commercial. I recognized how they were describing the uncontrollable crying episodes and how I was that patient; I was that person. After the commercial, I did some research and I read up on PBA, and upon receiving that information, made some print outs, made an appointment with my neurologist, he examined me, questioned me, asked me for my medical records, and when he got that, he noticed the TBI and that led to the PBA diagnosis and the prescription for NUEDEXTA. He mentioned that the potential side effects could be diarrhea, dizziness, cough, vomiting, weakness or ankle swelling. I was just relieved to try NUEDEXTA.

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Robert: I'm not back to a hundred percent, but with the diagnosis and the treatment of NUEDEXTA, I have fewer episodes and I feel like I'm in more control.

Onscreen Text: Robert Diaries, Treating PBA with NUEDEXTA®

Robert: After my accident, I went back to collecting baseball cards, and I was a good player too, so it was just my way of appreciating the game.

Robert: Trying to explain the symptoms that you're having, how they manifest, how they come about so that the doctors can help you manage it and then in turn get the NUEDEXTA prescription to help you with those symptoms.

Onscreen Text: Robert Diaries, Don't Give Up

Robert: It's already a difficult situation – it hampers your life – I don't want that, that's why I want to bring about awareness.

End Card:
NUEDEXTA Logo
Visit NUEDEXTAHCP.COM
THE ONLY FDA APPROVED TREATMENT PROVEN TO REDUCE PBA EPISODES.

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).

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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.”

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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.

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

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