

ADVANCED PATIENT SERVICES

PO Box 42886, Cincinnati, Ohio 45242 | Phone: 1-855-468-3339 | Fax: 1-877-788-4943



CHECKLIST TO COMPLETE ENROLLMENT FORM

PLEASE NOTE

Providing Incomplete or Incorrect Information May Delay Processing of Your Request

Fax fully completed forms to **1-877-788-4943** or mail to address on form

Do not return completed form to your AVANIR Sales Representative

Have questions? Call 1-855-468-3339 Monday – Friday, 8 AM – 7 PM ET

- Indicate all types of assistance requested
(e.g. if a PA was already submitted, circle *Appeals Assistance* at the top of the form)
- Ensure all Information in sections I to IV is entered fully and accurately
- Obtain **Two Signatures**: Confirm **HCP** and **patient/caregiver** have signed and dated form
Without Certification and Authorization forms will not be processed
- Include legible copy of patient's prescription insurance card (*front and back*)
or for LTC resident, legible copy of the resident's face sheet

Incomplete or Incorrect Information Delays Processing

- Attach any additional relevant documentation or clinical history information available for the patient or LTC resident to ensure appropriate utilization of NUEDEXTA
(e.g. *Confirmation of diagnosis of PBA, underlying neurologic condition, CNS-LS scores over time, frequency and duration of crying and laughing episodes, history of other conditions that may be contraindicated*)

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 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 with 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.

Please see additional Important Safety Information on reverse and full Prescribing Information included or visit www.NUEDEXTA.com

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CONTRAINDICATIONS (cont'd)

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 $\geq 3\%$ 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.