Important Safety Information

NUDEXTA® (dextromethorphan hydrobromide and quinidine sulfate) 20mg/10mg capsules are approved for the treatment of PseudoBulbar Affect (PBA). PBA is a medical condition that causes sudden, frequent and uncontrollable outbursts of crying and/or laughing in people living with certain neurologic conditions or brain injury. NUEDEXTA is not approved to treat emotional symptoms other than uncontrollable crying and/or laughing due to PBA.

Before you take NUEDEXTA, tell your doctor:

- If you are taking monoamine oxidase inhibitors (MAOIs), quinidine, or quinidine-related drugs. These can interact with NUEDEXTA causing serious side effects. MAOIs cannot be taken within 14 days before or after taking NUEDEXTA
- About all medicines, herbal supplements, and vitamins you take as NUEDEXTA and certain other medicines can interact causing side effects.
- If you have had heart disease or have a family history of heart rhythm problems. NUEDEXTA may cause serious side effects, including changes in heart rhythm. If you have certain heart problems, NUEDEXTA may not be right for you. Your doctor may test your heart rhythm (heartbeats) before you start NUEDEXTA.

While taking NUEDEXTA, call your doctor right away:

- If you feel faint or lose consciousness.
- If you experience lightheadedness, chills, fever, nausea, or vomiting as this may be a sign of an allergic reaction to NUEDEXTA.

The most common side effects of NUEDEXTA are diarrhea, dizziness, cough, vomiting, weakness, and swelling of feet and ankles. If you feel dizzy, be extra careful not to fall, especially if you have a hard time walking or a problem with falling. This is not a complete list of side effects. Tell your doctor about any side effect that bothers you or does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 800-FDA-1088.

For more information, click here for the Full Prescribing Information.