



TREATMENT GUIDE

NUEDEXTA[®]

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

**Inside: Ways to get the most
from treatment with NUEDEXTA**

**Please see Important Safety Information inside
and Brief Summary of Important Facts.**

NUEDEXTA.com

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GET THE MOST FROM TREATMENT WITH NUEDEXTA

You and your doctor have made the important decision to treat your PBA with NUEDEXTA, the first and only treatment approved by the FDA to treat PBA.

PBA (Pseudobulbar Affect) is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury. Treatment with NUEDEXTA is proven to reduce PBA episodes.

As you continue your treatment, it's important to follow your dosing routine and give your treatment time to work. It may also be helpful to keep track of your results.



What is NUEDEXTA approved for?

- NUEDEXTA is approved for the treatment of Pseudobulbar Affect (PBA). PBA is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury. PBA episodes are typically exaggerated or don't match how the person feels. PBA is distinct and different from other types of emotional changes caused by neurologic disease or injury.
- NUEDEXTA is only available by prescription.

ARE YOU FOLLOWING YOUR DOSING ROUTINE?

When you take the prescribed dose at the same time each day, you are keeping the right amount of medicine in your system which allows it to work properly.

For

WEEK 1

take **ONE CAPSULE** each morning.

This dose introduces NUEDEXTA to your body.

Starting

WEEK 2

on day eight, increase your dose to **TWO CAPSULES** per day—one in the morning, one in the evening, 12 hours apart.

This is your daily dose for the rest of your treatment.

Important Dosing Guidelines

- You can take NUEDEXTA with or without food.
- If you miss a dose, do not take a double dose. Take your next dose of NUEDEXTA at your usual time.
- Do not take more than 2 capsules in a 24-hour period. Make sure that you have approximately 12 hours in between your doses.

Check with your doctor to make sure that your prescription matches this dosing routine.

IMPORTANT SAFETY INFORMATION

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.

ARE YOU GIVING YOUR TREATMENT TIME TO WORK?

NUEDEXTA is meant to work over time. You should expect to see your best results by about 90 days.**

Average reduction in a 12-week clinical trial*

Week 12

82%

fewer episodes
compared to 45% on placebo**

Last 2 weeks

57%

were episode free
compared to 29% on placebo**

Patients taking NUEDEXTA experienced an average of 3.9 less episodes per day compared with 6.8 episodes per day before taking NUEDEXTA. Patients taking placebo experienced an average of 3.0 less episodes per day compared with 4.5 episodes per day before taking placebo.**

What might happen if you stop treatment

To continue the benefits of NUEDEXTA, take daily as directed by your physician. In a clinical trial, at the beginning of the second week of treatment, patients increased their NUEDEXTA dosage to 2 capsules each day. After the 12-week clinical trial was over, many patients were monitored for another 3 months. During the transition between trials, some patients had a gap in treatment. **Many of those who stopped saw their PBA symptoms increase after a 48-hour break in treatment.†** From time to time, your doctor may want to determine if you still need to take NUEDEXTA. **For some patients, PBA symptoms may improve on their own.**

*Researchers conducted a 12-week clinical trial. This trial was randomized and double-blind and enrolled 326 patients. NUEDEXTA is the first and only treatment approved by the FDA to treat PBA.

** Piroo EP, Brooks BR, Cummings J, et al. Dextromethorphan plus ultra low-dose quinidine reduces Pseudobulbar affect. *Ann Neurol*. 2010;68:693-702.

† Patients with ALS or MS who stopped NUEDEXTA treatment after the initial 12-week trial had their final CNS-LS scores compared to their scores at the beginning of a 12-week open-label extension trial. An increase in CNS-LS scores indicated a return of PBA symptoms.

WHAT ARE THE SIDE EFFECTS OF NUEDEXTA?

Some of the most common side effects when taking NUEDEXTA are:

- **Diarrhea**
- **Dizziness**
- **Coughing**
- **Vomiting**
- **Weakness**
- **Swelling of feet and ankles**

These side effects were each seen in less than 15% of patients taking NUEDEXTA in a clinical trial.* This is not a complete list of side effects. Tell your doctor about any side effects that bother you or do not go away.

*Piroo EP, Brooks BR, Cummings J, et al. Dextromethorphan plus ultra low-dose quinidine reduces pseudobulbar affect. *Ann Neurol.* 2010;68:693-702.



IMPORTANT SAFETY INFORMATION (CONTINUED)

Before you take NUEDEXTA, tell your doctor:

- If you have previously had an allergic reaction to dextromethorphan, quinidine or quinidine-like drugs.
- 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.
- If you have myasthenia gravis.

ARE YOU SEEING RESULTS?

Keeping track of the differences you see during treatment with NUEDEXTA will help you remember what changes you've noticed in comparison to life before treatment. This can help your doctor understand how NUEDEXTA is working for you.

How many PBA episodes are you having each day? Write them down in the Episode Tracker on the next page.

What differences have you seen in your daily routine due to a change in PBA episodes? Even small changes are important to track.

Share these notes with your doctor.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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 these may be signs of an allergic reaction to NUEDEXTA. Hepatitis has been seen in patients taking quinidine, an ingredient in NUEDEXTA.

EPISODE TRACKER

Write down the number of PBA episodes you have each day through your first 90 days of treatment.

I started taking NUEDEXTA on this day:

(month/day/year)

DAY 1-30

DAY 31-60

DAY 61-90

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CONTINUING YOUR TREATMENT WITH NUEDEXTA

By choosing to treat your PBA (Pseudobulbar Affect) with NUEDEXTA, you're taking a step to reduce the sudden crying and/or laughing episodes that may have left you feeling misunderstood and frustrated.

Continue treatment with NUEDEXTA as prescribed by your doctor so you can experience fewer PBA episodes. Be sure to write down the changes you see during treatment on the page provided and fill in the Episode Tracker each day. Refer to your doctor and this guide if questions arise during treatment.



IMPORTANT SAFETY INFORMATION (CONTINUED)

While taking NUEDEXTA, call your doctor right away:

- If you have unexplained bleeding or bruising. Quinidine, an ingredient in NUEDEXTA, can cause a reduction in the number of platelets in your blood which can be severe and, if left untreated, can be fatal.
- If you feel dizzy, since it may increase your risk of falling.
- If you have muscle twitching, confusion, high blood pressure, fever, restlessness, sweating, or shivering, as these may be signs of a potential drug interaction called serotonin syndrome.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

The most common side effects of NUEDEXTA are diarrhea, dizziness, cough, vomiting, weakness, and swelling of feet and ankles. 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.

Please see enclosed Brief Summary of Important Facts.

For more information:

CALL

1-855-468-3339

VISIT

NUEDEXTA.com

IMPORTANT FACTS

(Pronounced: new-DEX-tuh)

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ABOUT NUEDEXTA

- NUEDEXTA® is approved for the treatment of Pseudobulbar Affect (PBA). PBA is a medical condition that causes involuntary, sudden, and frequent episodes of crying and/or laughing in people living with certain neurologic conditions or brain injury. PBA episodes are typically exaggerated or don't match how the person feels. PBA is distinct and different from other types of emotional changes caused by neurologic disease or injury.
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DO NOT TAKE NUEDEXTA IF YOU

- Are taking other drugs that contain quinidine, quinine, or mefloquine.
- Have a history of allergic reactions or intolerance (including hepatitis, low blood cell count, or lupus-like syndrome) to quinidine, quinine, or mefloquine.
- Have ever been allergic to dextromethorphan (commonly found in some cough medicines).
- Are taking, or have taken, drugs called monoamine oxidase inhibitors (MAOIs). MAOIs cannot be taken within 14 days before or after taking NUEDEXTA.
- Have had heart disease or have a family history of heart rhythm problems.
- Are taking drugs such as thioridazine and pimozide that interact with NUEDEXTA and cause changes in heart rhythm.
- If you have certain heart conditions or are taking certain medicines, your doctor may test your heart rhythm (heartbeats) before you start NUEDEXTA.

NUEDEXTA MAY CAUSE SERIOUS SIDE EFFECTS

- Stop NUEDEXTA if these side effects occur:
 - Symptoms including lightheadedness, chills, fever, nausea, or vomiting may be a sign of an allergic reaction, or thrombocytopenia which if left untreated can be fatal.
 - Hepatitis has been seen in patients taking quinidine, an ingredient in NUEDEXTA.
 - Abnormal heart rhythm. Stop NUEDEXTA and tell your doctor immediately as it may be a sign of Torsades de Pointes.
- In some cases NUEDEXTA can interact with antidepressants causing confusion, high blood pressure, fever, restlessness, sweating, and shivering. Tell your doctor if you experience any of these side effects.
- Tell your doctor if you've ever been diagnosed with myasthenia gravis. If so, NUEDEXTA may not be right for you.

POSSIBLE COMMON SIDE EFFECTS OF NUEDEXTA

The most common side effects in patients taking NUEDEXTA were diarrhea, dizziness, cough, vomiting, weakness and swelling of feet and ankles.

- If you are unsteady on your feet or if you have fallen before, be careful while taking NUEDEXTA to avoid falling.
- **This is not a complete list of side effects.**
- **Tell your doctor if you have any side effect that bothers you or does not go away.**

TAKING NUEDEXTA ALONG WITH OTHER MEDICATIONS

- Tell your doctor about all medicines, supplements, and vitamins you take before starting NUEDEXTA.
- NUEDEXTA may interact with other medications causing potentially serious side-effects, and may affect the way NUEDEXTA or these other medicines work. Your doctor may adjust the dose of these medicines if used together with NUEDEXTA:
 - Antidepressants.
 - Certain heart or blood pressure medications. Your doctor may test your heart rhythm before you start NUEDEXTA.
 - Digoxin.
 - Alcohol. Limit alcohol intake while taking NUEDEXTA.
 - **These are not the only medicines that may cause problems when you take NUEDEXTA.**
- Before starting a new medicine, remind your doctor if you are taking NUEDEXTA.

ADDITIONAL IMPORTANT INFORMATION

- **If your PBA symptoms do not improve or if they get worse, contact your healthcare provider.**
- NUEDEXTA has not been studied in patients less than age 18 or in pregnant women. Tell your doctor if you may be pregnant.
- Nursing mothers: Because many drugs are excreted in human milk, discuss with your healthcare provider if you are nursing.
- Take NUEDEXTA exactly as your doctor prescribes it.
- You and your healthcare provider should talk regularly about whether you still need treatment with NUEDEXTA.
- NUEDEXTA may be taken with or without food.
- Keep NUEDEXTA and all medicines out of reach of children.
- The need for continued treatment should be reassessed periodically, as spontaneous improvement of PBA occurs in some patients.

NEED MORE INFORMATION?

This information about NUEDEXTA is important but is not complete. To learn more:

- Talk to your healthcare provider or pharmacist
- Visit www.Nuedexta.com for FDA-approved Prescribing Information or call 1-855-4NUEDEX (1-855-468-3339).

NEED PRESCRIPTION ASSISTANCE?

- Call 1-855-4NUEDEX (1-855-468-3339) to speak with a member of our support team for tips, tools and co-pay information.

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