Collegium Announces Extension of Nucynta Regulatory Exclusivity through July 2026

August 24, 2023

STOUGHTON, Mass., Aug. 24, 2023 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions, today announced that the U.S. Food and Drug Administration (FDA) has granted New Patient Population exclusivity for Nucynta®, an immediate release formulation of tapentadol. This grant extends the period of U.S. exclusivity for Nucynta from June 27, 2025 to July 3, 2026.

The exclusivity determination is based on data from pediatric trials which were submitted in response to the FDA's Pediatric Written Request to evaluate the use of Nucynta as a treatment for pain in pediatric patients aged 6 years and older.

Nucynta is currently approved in the U.S. for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults and pediatric patients aged 6 years and older with a body weight of at least 40kg.

“We believe that this grant of additional exclusivity recognizes the importance of Nucynta in the treatment of acute, severe pain,” said Thomas Smith, M.D., Collegium’s Chief Medical Officer. “We remain committed to the Nucynta Franchise, including through continued pursuit of a pediatric extension which would extend exclusivity of the entire Nucynta Franchise an additional six months, to December 2025 for Nucynta ER and January 2027 for Nucynta.”

About Collegium Pharmaceutical, Inc.

Collegium is a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. Collegium’s headquarters are located in Stoughton, Massachusetts. For more information, please visit the Company’s website at www.collegiumpharma.com.

NUCYNTA® (tapentadol) INDICATIONS AND USAGE

NUCYNTA® (tapentadol) tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage short term (acute) pain in adults and children 6 years of age and older who weigh at least 88 pounds (40 kg), when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse
  that can lead to death.

IMPORTANT SAFETY INFORMATION ABOUT NUCYNTA TABLETS

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF NUCYNTA TABLETS

Addiction, Abuse, and Misuse
Because the use of NUCYNTA tablets exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient’s risk prior to prescribing and reassess regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of NUCYNTA tablets, especially during initiation of NUCYNTA tablets or following a dose increase. To reduce the risk of respiratory depression, proper dosing and titration of NUCYNTA tablets are essential.

Accidental Ingestion
Accidental ingestion of even one dose of NUCYNTA tablets, especially by children, can result in a fatal overdose of tapentadol.

Risks From Concomitant Use With Benzodiazepines or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of NUCYNTA tablets and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Neonatal Opioid Withdrawal Syndrome
If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of Neonatal Opioid Withdrawal Syndrome which may be life threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)
Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.

Important information about NUCYNTA tablets:

- **Get emergency help or call 911 right away if you take too much NUCYNTA (overdose) tablets.** When you first start taking NUCYNTA tablets, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking NUCYNTA tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NUCYNTA tablets. They could die from taking it. Selling or giving away NUCYNTA tablets is against the law.
- Store NUCYNTA tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take NUCYNTA tablets if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking NUCYNTA tablets, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, opioid overdose or mental health problems
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

Tell your healthcare provider if you:

- **notice your pain getting worse.** If your pain gets worse after you take NUCYNTA tablets, do not take more NUCYNTA tablets without first talking to your healthcare provider. Tell your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking NUCYNTA tablets.
- **are pregnant or planning to become pregnant.** Use of NUCYNTA tablets for an extended period of time during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **are breastfeeding.** NUCYNTA tablets pass into breast milk and may harm your baby.
- are living in a household where there are small children or someone who has abused street or prescription drugs.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NUCYNTA tablets with certain other medicines can cause serious side effects that could lead to death.

When taking NUCYNTA tablets:

- Do not change your dose. Take NUCYNTA tablets exactly as prescribed by your healthcare provider.
  Use the lowest dose possible for the shortest time needed.
- For acute (short-term) pain, you may only need to take NUCYNTA tablets for a few days. You may have some NUCYNTA tablets left over that you did not use. See disposal information at the bottom of this section for directions on how to safely throw away (dispose of) your unused NUCYNTA tablets.
- Take your prescribed dose every 4-6 hours, at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking NUCYNTA tablets regularly, do not stop taking NUCYNTA tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused NUCYNTA Tablets by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking NUCYNTA tablets, DO NOT:

- Drive or operate heavy machinery, until you know how NUCYNTA tablets affect you. NUCYNTA tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with NUCYNTA tablets may cause you to overdose and die.

The possible side effects of NUCYNTA tablets:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help or call 911 right away if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all of the possible side effects of NUCYNTA tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information, go to** dailymed.nlm.nih.gov.

See full Prescribing Information, including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, and the Medication Guide accompanying this piece or at Nucynta.com/IRpi. Speak to your healthcare provider if you have questions about Nucynta.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as “predicts,” “forecasts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements related to our pursuit of a pediatric extension of exclusivity for the Nucynta franchise. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results, performance, or achievements to differ materially from the company's current expectations, including the risks described under the heading "Risk Factors" in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the SEC. Any

forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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