11960 Southwest 144th Street
Miami, Florida 33186
305-253-1916 ▼ Toll-Free: 888-253-5099
www.noven.com

PRESS RELEASE

Noven Provides Update on Daytrana® (methylphenidate transdermal system), CII Supply and Ongoing Efforts to Resolve Shortage

March 6, 2025 – Miami, FL and Jersey City, NJ -- Noven Pharmaceuticals. Inc., (Noven), announced an update regarding the current supply status of DAYTRANA, which is experiencing a temporary shortage, impacting all dosage strengths, due to shortage of an active ingredient. Availability is expected to resume mid-to-late 2025. Further details can be found on the FDA Drug Shortage Database, https://dps.fda.gov/drugshortages/activeingredient/methylphenidate-film-extended-release.

Patient care remains our highest priority, and we recognize the critical importance of DAYTRANA for individuals who rely on it. We are actively working with regulatory agencies and supply chain partners to mitigate the impact of this shortage and restore normal supply levels as quickly as possible.

If you have any questions, please contact Noven's Customer Information Hotline at 800-455-8070.

What is DAYTRANA?

DAYTRANA is a prescription central nervous system (brain) stimulant medicine used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in children and adolescents 6 to 17 years of age. DAYTRANA may help increase attention and decrease impulsive and hyperactive behavior in children with ADHD. It is not known if DAYTRANA is safe and effective in children under 6 years of age.

IMPORTANT SAFETY INFORMATION

Abuse, misuse, and addiction: DAYTRANA is a federally controlled substance (CII) because it contains methylphenidate that can be a target for people who abuse prescription medicines or street drugs.

Keep DAYTRANA in a safe place to protect it from theft. Never give your DAYTRANA to anyone else because it may cause death or harm them. Selling or giving away DAYTRANA may harm others and is against the law. Tell your healthcare provider if your child has ever abused or been dependent on alcohol, prescription medicines, or street drugs.

DAYTRANA should not be used if your child is:

- Allergic to methylphenidate or any of the ingredients in DAYTRANA.
- Taking, or has stopped taking within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

DAYTRANA may cause serious side effects including:

- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease. Tell your child's healthcare provider (HCP) if your child has any heart problems, heart disease, or heart defects. **Remove the DAYTRANA transdermal system (patch) and call your child's HCP or go to the nearest emergency room right away if your child has any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with DAYTRANA.**
- **Increased blood pressure and heart rate.** Your child's healthcare provider should check their blood pressure and heart rate regularly during treatment with DAYTRANA.
- **Mental (psychiatric) problems.** Including new or worse behavior or thought problems; new or worse bipolar illness; new psychotic symptoms (such as hearing voices or seeing or believing things that are not real), or manic symptoms. Tell your child's HCP about any mental problems they have or about family history of suicide or depression, bipolar illness, or depression. **Call your child's HCP right away if your child has any new or worsening mental symptoms or problems while using DAYTRANA.**
- **Seizures.** Your child's HCP may stop treatment with DAYTRANA if they have a seizure.
- **Painful and prolonged erections (priapism).** Priapism that may require surgery has happened in people who take products that contain methylphenidate. If your child develops priapism, get medical help right away.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).** Fingers or toes may feel numb, cool, or painful. Fingers and toes may change color from pale, to blue, to red. Tell your child's HCP if your child has any numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes. **Call your child's HCP right away if they have any signs of unexplained wounds appearing on fingers or toes during treatment with DAYTRANA.**
- **Slowing of growth (height and weight) in children.** Your child should have their height and weight checked often during treatment with DAYTRANA.
- **Eye problems (increased pressure in the eye and glaucoma).** Call your child's HCP right away if they develop changes in their vision, eye pain, swelling, or redness.
- **New or worsening tics or worsening Tourette's syndrome.** Tell your child's HCP if they get any new or worsening tics or worsening Tourette's syndrome during treatment with DAYTRANA.
- **Loss of skin color.** Call your child's HCP right away if they have changes in skin color. DAYTRANA may be stopped if your child has changes in skin color.
- **Allergic skin rash.** Stop using DAYTRANA and tell your child's HCP right away if they develop swelling or blisters at or around the application site.

Before taking DAYTRANA, tell your HCP about all the medications your child takes and their medical conditions, including if they:

- Are pregnant or plan to become pregnant. DAYTRANA may harm the unborn baby. There is a pregnancy registry for females who are exposed to DAYTRANA during pregnancy. The purpose of the registry is to collect information about the health of women exposed to DAYTRANA and their baby. To learn more about registering with the National Pregnancy Registry of Psychostimulants Medications call **1-866-961-2388** or visit online at **https://womensmentalhealth.org/adhd-medications/**.
- Are breastfeeding or plan to breastfeed. DAYTRANA passes into breast milk. Talk to your HCP about the best way to feed the baby during treatment with DAYTRANA.

The most common side effects of DAYTRANA in children 6 to 12 years old include: Decreased appetite, trouble sleeping, nausea, vomiting, weight loss, tics; changes in mood, and trouble eating.

The most common side effects of DAYTRANA in children 13 to 17 years old include: Decreased appetite, nausea, trouble sleeping, weight loss, dizziness, stomach pain, and trouble eating.

DAYTRANA may also cause skin problems where it is applied (redness, small bumps, itching).

Please read **Medication Guide** and **Full Prescribing Information** including the Boxed Warning.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/medwatch or call 1-800-FDA-1088.