FIRST TIME GENERIC APPROVAL

Brand Name	Daytrana®
Generic Name	methylphenidate
Drug Manufacturer	Mylan Pharmaceuticals Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

March 14, 2022

LAUNCH DATE

June 27, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 206497

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

- Methylphenidate transdermal system is a central nervous system (CNS) stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD).
- Children (ages 6-12): the efficacy of methylphenidate transdermal system in ADHD was established in two 7-week controlled trials in children.
- Adolescents (ages 13-17): the efficacy of methylphenidate transdermal system in ADHD was established in one 7-week, controlled study in adolescents.

MECHANISMS OF ACTION

Methylphenidate is a central nervous system (CNS) stimulant. Its mode of therapeutic action in attention deficit hyperactivity disorder (ADHD) is not known.

DOSE FORM AND STRENGTH

Transdermal System: 10 mg/9 hours (1.1 mg/hr), 15 mg/9 hours (1.6 mg/hr), 20 mg/9 hours (2.2 mg/hr), 30 mg/9 hours (3.3 mg/hr)

DOSE & ADMINISTRATION

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- The recommended starting dose for patients new to or converting from another formulation of methylphenidate is 10 mg.
- Methylphenidate transdermal system should be applied to the hip area (using alternating sites) 2 hours before an effect is needed and should be removed 9 hours after application. methylphenidate transdermal system may be removed earlier than 9 hours if a shorter duration of effect is desired or late day side effects appear.
- Dosage should be titrated to effect. Dose titration, final dosage, and wear time should be individualized according to the needs and response of the patient.