



Prior Authorization Approval Criteria Daytrana (methylphenidate transdermal system)

Generic name: methylphenidate transdermal system
Brand name: Daytrana
Medication class: CNS stimulant
FDA-approved use: Attention deficit hyperactivity disorder (ADHD)
Available dosage forms: transdermal patch (10 mg, 15 mg, 20 mg, 30 mg)

Usual dose range: The patch should be applied 2 hours prior to the needed effect and should be removed 9 hours after application. Dose should be titrated to effect. Dose titration, final dosage and wear time should be individualized according to the needs and response of the patient. The recommended dose titration schedules are based on the following table from the package insert:

Upward titration, if response is not maximized

	Week 1	Week 2	Week 3	Week 4
Patch size	12.5 cm ²	18.75 cm ²	25 cm ²	37.5 cm ²
Nominal delivered dose (mg/9 hours)	10 mg	15 mg	20 mg	30 mg
Delivery rate	1.1 mg/hr	1.6 mg/hr	2.2 mg/hr	3.3 mg/hr

Duration of therapy: Indefinite
Approximate cost: \$143.28 per month for all strengths
(based on AWP 2006)

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Clinically diagnosed ADHD.
 - Must be greater than 6 years of age.
 - Failed a long-acting oral methylphenidate product.
 - Failed long-acting Adderall.
- OR**
- Inability to take oral formulations.

Cautions: Erythema is common at the site of application. However, if it is accompanied by edema, papules, vesicles, or does not improve within 48 hours or spreads beyond the patch site, it could be evidence of contact dermatitis and sensitization.

Contraindications:

- Patients with marked anxiety, tension, and agitation.
- Hypersensitivity to any product components.
- Glaucoma.
- Motor tics or a family history or diagnosis of Tourettes syndrome.
- Use with MAO inhibitors.

Not approved if:

- Does not meet the above stated criteria
- Has any contraindications to the use of methylphenidate

Special considerations:

- One clinical study showed that about 20% of patients experienced skin irritation.
- Was previously rejected in 2003 by the FDA because the patch "overmedicated children" and led to unacceptable adverse events "not associated with other once-a-day products available." This is why children are to wear the patch for 9 hours rather than 12 hours.
- Daytrana's packaging says that its use may lead to sensitization to methylphenidate. In one study, 13.5% of patients became sensitized to Daytrana following continuous exposure to the patch at the same application site for 3 weeks. When the patch sites were rotated daily, no cases of sensitization were reported. The company warns that patients who require oral methylphenidate after developing sensitization to Daytrana should be closely monitored when beginning oral therapy. It is possible that a child may not be able to take methylphenidate in any form following sensitization to the patch.
- In December 2005, advisory panels worried about tests showing that as many as 22% of clinical trial subjects using the patch became so sensitive to the drug that they could not take methylphenidate at all.
- Clinical comparison between the patch and oral agents used are unavailable.
- Side effects were comparable with other stimulants with the exception of a small increase in tics, or involuntary movements like twitching.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/13/06