Daytrana

(methylphenidate)

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Full Prescribing Information	DailyMed Drug Information

Summary

Daytrana is a long-acting methylphenidate CNS stimulant delivered as an adhesive transdermal patch worn on the hip, approved for ADHD in patients 6 to 17 years only. Dose is set by patch size and by wear time, so a parent can shorten the day by removing it early, which no oral product allows. It is also the only methylphenidate carrying a risk of permanent skin depigmentation. Schedule II; brand and generic.

Forms & Strengths

- Transdermal system (patch, hip): 10 mg/9 h, 15 mg/9 h, 20 mg/9 h, 30 mg/9 h

Dosing

- **Age:** 6-17 y/o; pediatric only
- **Onset:** ~ 2 hours after application
- **Duration:** through 12 hours after application, on a 9-hour wear time
- **Release Profile:** continuous transdermal delivery from an adhesive matrix; no IR fraction and no bead or coat split
- **Initial Dose:** 10 mg/9 h patch (12.5 cm2) once daily, including when converting from an oral methylphenidate
- **Titration:** one patch size every 7 days, in the order 10, 15, 20, 30 mg/9 h
- **Max Dose:** 30 mg/9 h
- **Considerations:** Wear time is a second dosing variable: remove at 9 hours, or earlier for a shorter day. Never cut a patch. Heat or inflamed skin under the patch can double or

triple absorption.

Pharmacology

- **Mechanism:** Blocks presynaptic dopamine and norepinephrine reuptake at DAT and NET; does not meaningfully promote catecholamine release at therapeutic doses
- **Delivery / Release:** Three-layer adhesive matrix; peak plasma ~10 h single dose, ~8 h on repeat. No food effect. Absorption rises with repeat dosing over the first four weeks.
- **Metabolism:** De-esterified to ritalinic acid, inactive. No CYP pathway. Half-life after removal 4 to 5 hours.
- **Class Positioning:** Bypassing first pass leaves l-methylphenidate at 40% to 46% of the d-isomer instead of near zero, so conversion from an oral product restarts at the smallest patch.

Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 6-17 y/o. No adult indication.

Off-Label Uses

- **Where the evidence does not support use.**
  - **ADHD under 6 y/o** (ICD-10: F90.x): the label records evidence against, with higher exposure and more weight loss; insufficient. (AHRQ 2024)
  - **Sites other than the hip:** absorption differs and is not adequately studied; insufficient.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction, which can lead to substance use disorder, overdose and death.
- **Chemical leukoderma, specific to this product:** persistent depigmentation at, around and sometimes distant from the site. **It may be permanent.** Discontinue for good.
- **Contraindicated:**
  - Hypersensitivity to methylphenidate or any system component, adhesives included; the reaction may be to the system, not the drug.
  - Concomitant MAOI, or within 14 days of stopping one.

- **Contact sensitization** (0.3% of 305 children): a sensitized patient may react systemically to oral methylphenidate, and some cannot take it.
- **Use with caution:**
  - Personal or family history of vitiligo, because of chemical leukoderma.
  - Structural cardiac abnormality, cardiomyopathy, serious arrhythmia or coronary disease; avoid.
  - Prior seizures or EEG abnormality; this label carries a Seizures warning the oral labels do not.
  - Pre-existing hypertension; expect a rise of 2 to 4 mmHg and 3 to 6 bpm.
  - Psychotic or bipolar disorder; tics or Tourette's (tic ran 7.1% versus 0%).
  - Hyperopia, open-angle glaucoma, or raised intraocular pressure; substance use disorder in patient or household.
- **Screen before starting:**
  - Cardiac history, family history of sudden death or arrhythmia, and exam.
  - History of tics, vitiligo, eczema or adhesive reactions; inspect the hip sites. Seizure or EEG history; risk factors for mania.
  - Whether the household can manage a timed daily application and removal; abuse risk; baseline growth, vitals and CBC.

Drug Interactions

- **Coumarins, anticonvulsants, TCAs and SSRIs** (warfarin; phenobarbital, phenytoin, primidone): metabolism may be inhibited. Reduce their dose and monitor levels, or INR.
- **MAOIs:** hypertensive crisis. Do not co-prescribe; allow 14 days after stopping.
- **External heat, which behaves like an interaction:** hair dryers, heating pads, electric blankets, hot tubs and prolonged sun raise absorption more than 2-fold; inflamed skin about 3-fold.
- **Antihypertensives:** effectiveness may fall; recheck blood pressure and adjust.
- **Halogenated anesthetics:** sudden intraoperative pressure and rate rise. Apply no patch on the day of surgery.
- **Risperidone:** a dose change either way may raise EPS risk; monitor across any change. **Serotonergic agents:** serotonin syndrome is postmarketing only here, so counsel on symptoms rather than avoid.

Administration

- **Timing:** apply to the hip 2 hours before an effect is needed; remove 9 hours later. Record both times on the carton chart.
- **Wear time is a dose control:** remove earlier for a shorter day or late-day effects.
- **Site:** clean, dry hip skin, not oily or irritated; avoid the waistline, alternate hips daily.

- Press firmly with the palm for 30 seconds at the edges. **Never cut a patch.** Discard one whose liner tore or took adhesive with it.
- **If a patch falls off,** apply a new one at a fresh site; the day still ends at 9 hours. Do not tape or re-stick a patch.
- **Removal:** peel slowly; work mineral oil under a stubborn edge. **Never use acetone or nail polish remover.**
- **Disposal:** used patches retain drug. Take-back site, or fold adhesive-to-adhesive and flush. A caregiver applies and removes it for children.
- **Switching from an oral methylphenidate** (Concerta or any other): start at 10 mg/9 h.

  Xelstrym is a dextroamphetamine patch, not interchangeable. Do not refrigerate; store securely, preferably locked.

Side Effects

- **Common in children 6-12** (n=98 vs 85, 7 weeks): decreased appetite 25.5% vs 4.7%, insomnia 13.3% vs 4.7%, nausea 12.2% vs 2.4%, weight decreased 9.2% vs 0%, tic 7.1% vs 0%. Adolescent rates similar. Site erythema is near-universal and minor.
- **Serious:**
  - **Chemical leukoderma,** possibly permanent, including at sites distant from the patch; and contact sensitization. Discontinue permanently for either.
  - Sudden death with structural cardiac disease; avoid the drug in that group.
  - Seizures; discontinue if one occurs. New psychosis or mania, ~0.1% pooled; consider discontinuing.
  - Priapism, which may require surgery, also during drug holidays. Peripheral vasculopathy including Raynaud's; reduce dose or stop.
  - Growth suppression: ~2 cm and 2.7 kg less over 3 years. Interrupt if growth stalls.
  - Acute angle closure glaucoma; new or worsening tics; angioedema and anaphylaxis; rare NMS; abnormal liver function.

Monitoring & Labs

- **Skin, for depigmentation:** examine the hips at every visit, minimum every 3 months, and ask about a pale patch anywhere on the body. Stop at the first sign.
- **Skin, for sensitization:** at every visit; escalate if erythema carries edema or vesicles past 48 hours.
- **Hematologic:** CBC, differential and platelets at baseline and at least annually. Labeled on Daytrana alone.
- **Application and removal times:** review the chart at every visit; drift in the removal hour explains most lost effect.
- **Weeks 2 to 4:** reassess tolerability at 4 weeks even without a size change; absorption rises with repeat dosing.

- **Cardiovascular and growth:** blood pressure, heart rate, height, weight and BMI at baseline, each size change, and every 6 months.
- **Psychiatric, tics, seizures and digits:** at every visit and size change; stop if a seizure occurs.
- **Abuse and diversion:** count patches against days at each refill and check the state PDMP per state requirement.

Discontinuation & Taper

- May be stopped abruptly; the label gives no taper schedule.
- **The offset is delayed.** Absorption continues from the skin depot for hours, so a patch off at 4 p.m. does not stop working at 4 p.m.
- **Shortening wear time is a legitimate step-down,** and the right lever for evening insomnia rather than a smaller patch.
- **Discontinue permanently for chemical leukoderma,** and stop for suspected sensitization or a seizure.
- After prolonged use expect withdrawal: dysphoria, fatigue, vivid dreams, sleep change, increased appetite. Drug holidays are simply a day without a patch.

Pregnancy & Lactation

- **Pregnancy:** Human data insufficient to identify a risk. No reproduction studies with the transdermal system; oral data showed spina bifida in rabbits at 200 mg/kg/day. Stimulants reduce placental perfusion.
- **Lactation:** Present in milk; infant receives 0.16% to 0.7% of the maternal weight-adjusted dose. Monitor for agitation, insomnia, poor feeding and low weight gain. (LactMed 2025)
- **Milk supply:** Methylphenidate lowers prolactin; large doses may interfere before lactation is established. (LactMed 2025)
- **Exposure Registry:** National Pregnancy Registry for ADHD Medications, 1-866-961-2388, womensmentalhealth.org/adhd-medications.

Counseling Points

- **Counsel the family on:**
  - **Watching for any pale or white patch of skin anywhere on the body, not only where the patch was.** It can be permanent and must be reported the day it is noticed.
  - Applying two hours before it is needed, and writing the removal time down.

    - Taking it off early being a legitimate adjustment, and that the effect does not stop when it comes off.
    - Redness being normal; swelling, blisters or spreading redness being a reason to call.
    - Alternating hips daily, off the waistline, and keeping heat off the site: no hair dryers, heating pads or long sun, which can double the dose absorbed.
    - Never cutting a patch; if one falls off, a fresh site, and the day still ends at 9 hours.
    - Removing adhesive with olive oil, never nail polish remover, and folding a used patch sticky sides together to dispose of it.
- **Advise them to call for:**
    - Any white or pale patch of skin, at the site or anywhere else.
    - Swelling, blisters, or redness spreading beyond the patch edge.
    - Chest pain, fainting, or a racing heart that does not settle.
    - A seizure, new hallucinations, or new fearful thinking.
    - Numbness or colour change in the fingers or toes; a new or worse tic.
    - Weight loss over a few weeks, or a patch that has gone missing.
    - A painful erection lasting more than a few hours, a surgical emergency.

References

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