

MEDICATION GUIDE
Daytrana® (day-TRON-ah)
(methylphenidate transdermal system) CII

Only Use Daytrana on Your Skin

Important:

Daytrana is a controlled substance (CII) because it can be abused or lead to dependence. Keep Daytrana in a safe place to protect it from theft. Selling or giving away Daytrana may harm others and is against the law.

Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicine or street drugs.

Read this Medication Guide before you start using Daytrana and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about Daytrana?

Daytrana is a central nervous system (brain) stimulant medicine. Serious side effects have been reported with Daytrana or other stimulant medicines, including:

1. Heart problems, including:

- sudden death in people who have heart problems or heart defects
- stroke and heart attack in adults
- increased blood pressure and heart rate

Your doctor should check you carefully for blood pressure and heart problems before you start and while you are using Daytrana.

Remove the Daytrana patch and call your doctor right away if you have any

- **signs of heart problems such as:**
- chest pain
- shortness of breath
- fainting

2. Mental (psychiatric) problems, including:

- new or worse aggressive behavior, hostility, anger, or irritability
- new or worse bipolar illness or mania (an extreme increase in activity or talking)
- new or worse psychosis (hearing or seeing things that are not real, being suspicious or distrustful, believing things that are not true)
- other unusual or extreme changes in behavior or mood

Tell your doctor right away if you have any new or worsening mental problems while using Daytrana.

What is Daytrana?

Daytrana is a prescription medicine used to treat Attention Deficit Hyperactivity Disorder (ADHD) in people 6 to 17 years old. Daytrana is a central nervous system (brain) stimulant medicine. Daytrana may help you have better attention and less impulsive and hyperactive behavior. Daytrana is a patch that you apply to your skin on your hip. Daytrana is used as part of a total treatment program for ADHD that may also include counseling or other treatments.

It is not known if Daytrana is safe and effective in children younger than 6 years.

Who should not use Daytrana?

Do not use Daytrana if you:

- are very anxious, tense, or agitated
- have glaucoma
- have tics (repeated movements or sounds that cannot be controlled)
- have Tourette's Syndrome or a family history of this syndrome
- are taking or have taken a monoamine oxidase inhibitor (MAOI) medicine within the past 2 weeks. Do not take a MAOI medicine for at least 2 weeks before using Daytrana. Ask your doctor or pharmacist if you are not sure if any of your medicines are MAOIs.
- are allergic to methylphenidate or any other ingredients in Daytrana. See "What are the ingredients in Daytrana?" for a complete list of ingredients.

Talk to your healthcare provider before taking this medicine if you have any of these conditions.

What should I tell my doctor before using Daytrana?

Before you start using Daytrana, tell your doctor if you have:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- seizures or have had an abnormal brain wave test (EEG)
- skin problems such as eczema or psoriasis, or have skin reactions to soaps, lotions, make-up, or adhesives (glues)
- are pregnant or plan to become pregnant. It is not known if Daytrana will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast feeding or plan to breast feed. It is not known if Daytrana passes into your breast milk. You and your doctor should decide if you will take Daytrana or breastfeed.

Tell your doctor about all of the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Daytrana and certain other medicines may affect each other, causing serious side effects.

Especially tell your doctor if you take:

- a monoamine oxidase inhibitor (MAOI) medicine See “Who should not take Daytrana?”
- medicines to treat depression
- medicines to treat seizures
- a blood pressure medicine
- a blood thinner medicine
- cold or allergy medicines that contain decongestants
- clonidine (Jenloga, Catapres)

Know the medicines that you take. Keep a list of them to show your doctor and pharmacist. Do not start any new medicine while using Daytrana without talking to your doctor first.

How should I use Daytrana?

- Use Daytrana exactly as your doctor tells you to.
- Your doctor may change your dose if needed.
- Apply Daytrana to your hip 2 hours before an effect is needed.
- Do not wear Daytrana longer than 9 hours a day.
- Apply Daytrana to a different hip each day
- Do not cut Daytrana patches.
- Parents or caregivers should apply and remove Daytrana for their child if the child is not responsible enough to do so
- Your doctor may stop Daytrana treatment to check your ADHD symptoms.
- Your doctor may do certain blood tests and check your heart and blood pressure while you use Daytrana.
- If you forget to apply a patch in the morning, you may apply the patch later in the day. You should remove your patch at the usual time of day to lower the chance of side effects later in the day.
- If you have loss of appetite or trouble sleeping in the evening, ask your doctor if you can take the patch off earlier in the day.
- Contact with water while bathing, swimming, or showering can make the patch not stick well or make it fall off. If your patch falls off, **do not** touch the sticky side of the patch with your fingers. You may apply a new patch to a different area on the same hip. If you have to replace a patch that has fallen off, the total wear time for the first and second patch should not be more than a total of 9 hours in 1 day. Do not reapply the same patch that fell off.
- **If you wear Daytrana longer than 9 hours, or if you wear more than 1 patch at a time, you have used too much Daytrana. Remove all Daytrana patches and wash the application sites right away. Call your local poison control center or go to the nearest hospital emergency room right away if you have:**
 - **vomiting**

- **agitation**
 - **shaking**
 - **confusion or mental changes**
 - **see things that are not there (hallucinations)**
 - **sweating**
 - **redness in your face**
 - **headache**
 - **heartbeat changes**
- Read the Patient Instructions for Use at the end of this Medication Guide.

What should I avoid while using Daytrana?

- Do not put any medicine, cream, or lotion on your hip before you apply the Daytrana patch. Medicines, creams or lotions may affect how the patch sticks to your skin and how the medicine is absorbed from the patch.
- Do not use bandages, tape, or other household adhesives (glue) to hold the patch onto your skin.
- **Do not use hair dryers, heating pads, electric blankets, heated water beds or other heat sources while wearing a Daytrana patch. Too much medicine can pass into your body and cause serious side effects.**
- Do not drive, operate heavy machinery or do other dangerous activities until you know how Daytrana affects you.

What are possible side effects of Daytrana?

Daytrana may cause serious side effects, including:

- See **“What is the most important information I should know about Daytrana?”**
- **Seizures.** This usually happens in people with a history of seizures.
- **Slowing of growth (weight and height).** You should have your height and weight checked while using Daytrana.
- Eyesight changes or blurred vision
- **Allergic skin rash.**
Stop using Daytrana and see your doctor right away if you have swelling or blisters at or around the application site. You may have a skin allergy to Daytrana. People who have skin allergies to Daytrana may develop an allergy to all medicines that contain methylphenidate, even those methylphenidate medicines that are taken by mouth.

The most common side effects of Daytrana include:

- | | |
|--|--------------------|
| ● skin problems where you apply Daytrana (redness, small bumps, itching) | ● stomach pain |
| ● poor appetite | ● weight loss |
| ● nausea | ● tics |
| ● vomiting | ● trouble sleeping |
| | ● mood swings |
| | ● dizziness |

Tell your doctor if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of Daytrana. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Daytrana?

- Store Daytrana between 59° F to 86° F (15° C to 30° C).
- Do not store Daytrana in the refrigerator or freezer.
- Keep Daytrana patches in their unopened pouches until you are ready to use them.
- Use or throw away the patches within 2 months after you open the sealed tray or outer pouch.

Keep Daytrana and all medicines out of the reach of children.

General information about Daytrana

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Daytrana for a condition for which it was not prescribed. Do not give Daytrana to other people, even if they have the same symptoms that you have. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Daytrana. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Daytrana that is written for health professionals.

For more information, go to www.daytrana.com, or call 1-800-828-2088.

What are the ingredients in Daytrana?

Active ingredient: methylphenidate

Inactive ingredients: acrylic adhesive, silicone adhesive

Instructions for Applying Daytrana

1. Daytrana Dosing Chart

Each carton of Daytrana contains a Daytrana Dosing Chart to help you keep track of your patch including:

- when you apply patch to the skin on your hip each morning
- when you remove the patch

- how and where you threw the Daytrana patch away

To use the Daytrana Dosing Chart, follow these instructions:

- Each day, when a new Daytrana patch is applied to your hip, write down the date and time that you applied the patch.
- Use the Daytrana schedule below so you can decide when to remove the patch. For example, if the patch is applied to the skin at 6:00 a.m., remove the patch at 3:00 p.m. on the same day. After you remove and throw away the patch, write down the time you removed the patch and how and where you threw it away.
- If the patch you placed on your child is missing, ask your child:
 - when the patch came off
 - how the patch came off
 - where the patch is

Daytrana Schedule for 9 Hour Dosing

If you put the patch on at:	On the same day, remove the patch at:
5:00 a.m.	2:00 p.m.
6:00 a.m.	3:00 p.m.
7:00 a.m.	4:00 p.m.
8:00 a.m.	5:00 p.m.
9:00 a.m.	6:00 p.m.
10:00 a.m.	7:00 p.m.
11:00 a.m.	8:00 p.m.
12:00 p.m.	9:00 p.m.

2. Where to apply Daytrana

- Apply patch to your hip area. Do not put the patch near your waist. Clothing and movement may make your patch rub off (See Figure A).
- Use your other hip when you apply a new patch the next morning. Make sure there is no redness, small bumps or itching at the site where the patch is going to be applied.

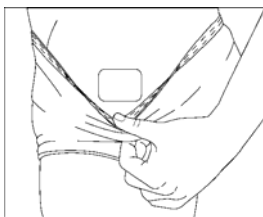


Figure A

3. Before you apply Daytrana

Make sure your skin:

- is clean (freshly washed), dry, and cool
- does not have any powder, oil, or lotion
- does not have any cuts and irritation (rashes, inflammation, redness, or other skin problems).

4. How to apply Daytrana

- Open the sealed tray or outer pouch and throw away the small packet (drying agent).
- Each patch is sealed in its own protective pouch.
- Carefully cut the protective pouch open with scissors, being careful not to cut the patch. **Do not use patches that have been cut or damaged in any way (See Figure B).**

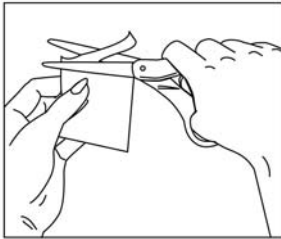


Figure B

- Remove the patch from the protective pouch.
- Look at the patch to make sure it is not damaged. The patch should separate easily from the protective liner. Throw away the patch if the protective liner is hard to remove.

The Daytrana patch has 3 layers. The 3 layers are pictured below. The pictures show both sides of the patch:

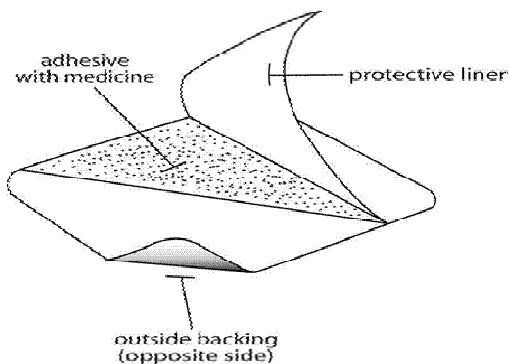


Figure C

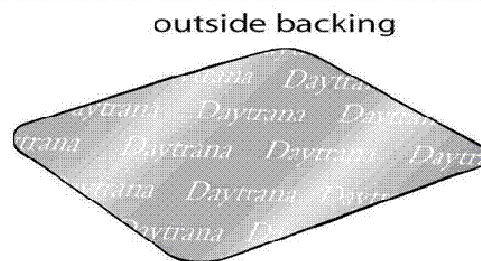


Figure D

Layers:

- **Protective liner.** The protective liner is the layer that you remove before you put the patch on (See Figure C).

- **Adhesive with medicine.** The adhesive with medicine is the layer that sticks to your skin (See Figure C).
 - **Outside backing:** The outside backing is the layer that you see after you put the patch on your skin. The word “Daytrana” is printed on this layer (See Figure D).
- **Apply the patch right away after you remove the patch from protective pouch.**
 - Hold the patch with the hard protective liner facing you. The word Daytrana will appear backwards.
 - **Gently** bend the patch along the faint line and **slowly peel** half the liner, which covers the sticky surface of the patch (See Figure E).

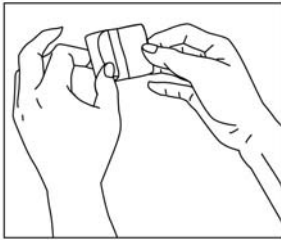


Figure E

- Avoid touching the sticky side of the patch with your fingers.
- If you accidentally touch the sticky side of the patch, apply the patch, then wash your hands right away so that the medicine does not go into the skin on your hands.
- Using the other half of the protective liner as a handle, apply the sticky side of the patch to the selected area of the child’s hip (See Figure F).

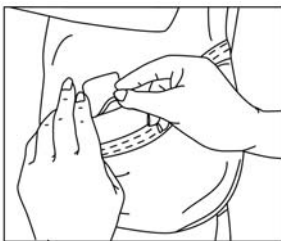


Figure F

- Press the sticky side of the patch firmly into place and smooth it down.
- While you are still holding the sticky side down, gently fold back the other half of the patch.
- Hold an edge of the remaining protective liner and **slowly peel** it off (See Figure G).

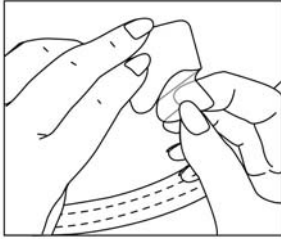


Figure G

- After the protective liner is removed, there should not be any adhesive (glue) sticking to the liner.



Figure H

- **Press the entire patch firmly into place with the palm of your hand over the patch for about 30 seconds (See Figure H).**
- Make sure that the patch firmly sticks to your skin.
- Gently rub the edges of the patch with your fingers to make sure the patch sticks to your skin.
- Wash your hands after you apply your patch.
- Write the time you applied your patch on the dosing chart on the carton. Use the dosing schedule so you know what time you should remove your patch.

5. **How to remove and throw away Daytrana**

- When you remove the patch, peel it off slowly. If the patch is too sticky on your skin and you need something to help you remove it:
 - Gently apply an oil-based product (petroleum jelly, olive oil, or mineral oil) to the patch edges. Gently spread the oil underneath the patch edges.
 - Apply an oil-based product or lotion to your skin if any adhesive (glue) remains after you remove your patch. This will gently loosen and remove any adhesive that is left over.
 - If you still can not easily remove the patch, ask your doctor or pharmacist about what to do for this problem.

- Fold the used Daytrana patch in half and press it together firmly so that the sticky side sticks to itself. **Flush the used patch down the toilet or put the patch in a container with a lid right away.**
- Do not flush the protective pouches or the protective liners down the toilet. These items should be thrown away in a container with a lid.
- Wash your hands after you handle the patch.
- After you remove the patch and throw the patch away, write down the time on the dosing chart.
- Safely throw away any unused Daytrana patches that are left over from the prescription as soon as they are no longer needed.

To safely throw away the patches:

- Remove the leftover patches from their protective pouches and remove the protective liners.
- Either fold the patches in half with the sticky sides together, and flush the patches down the toilet, **or**
- throw the patches away in a container with a lid.

Manufactured for Shire US Inc., Wayne, PA 19087 by Noven Pharmaceuticals, Inc., Miami, FL 33186.

© 2010 Shire Pharmaceuticals Ireland Limited.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised 06/2010