

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

Important: Only Use on Skin

Read the Medication Guide that comes with Daytrana™ before you or your child starts using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with Daytrana™.

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

Daytrana™ is a stimulant medicine. The following have been reported with use of Daytrana™ (methylphenidate transdermal system) or other stimulant medicines:

1. Heart-related problems:

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

Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting Daytrana™.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with Daytrana™.

Remove patch immediately and call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while using Daytrana™.

2. Mental (Psychiatric) problems:

All Patients

- new or worse behavior and thought problems
- new or worse bipolar illness
- new or worse aggressive behavior or hostility

Children and Teenagers

- new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

Tell your doctor about any mental problems you or your child has, or about a family history of suicide, bipolar illness, or depression.

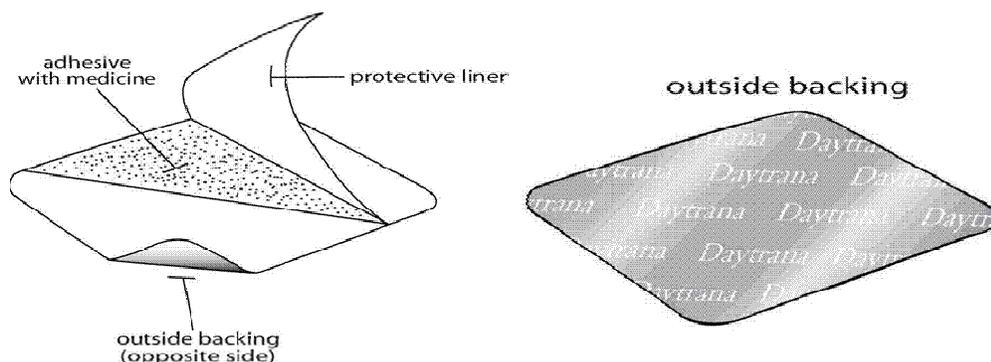
Call your doctor right away if you or your child has any new or worsening mental symptoms or problems while using Daytrana™, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What Is Daytrana™?

Daytrana™ is a central nervous system (CNS) stimulant prescription medicine. Daytrana™ is a skin patch that releases the medication contained in the adhesive (glue) through clean and intact skin areas into the bloodstream when applied to the skin on the hips. **It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).** Daytrana™ may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Daytrana™ should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

The Daytrana™ patch has 3 layers. The 3 layers are displayed and described in the figures below. The figures below display both sides of a patch:



- **Protective liner:** the layer that is removed prior to applying the patch to the skin.
- **Adhesive with medicine:** After the protective liner is removed, this is the side of the patch that sticks to the skin.
- **Outside backing:** This is what you will see after the patch is put on the skin. The word “Daytrana™” is printed on this side.

Daytrana™ is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Daytrana™ in a safe place to prevent misuse and abuse. Selling or giving away Daytrana™ may harm others, and is against the law.

Tell your doctor if you or your child has (or has a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not use Daytrana™?

Daytrana™ should not be used if you or your child:

- is very anxious, tense, or agitated
- has an eye problem called glaucoma
- has tics or Tourette’s syndrome, or a family history of Tourette’s syndrome. Tics are hard to control repeated movements or sounds.
- is taking or has taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- is allergic to anything in Daytrana™. Daytrana™ is a skin patch that contains methylphenidate in an acrylic and silicone adhesive (glue).

Daytrana™ should not be used in children less than 6 years old because it has not been studied in this age group.

Daytrana™ may not be right for you or your child. Before starting Daytrana™ tell your or your child’s doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette’s syndrome
- 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)

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can Daytrana™ be used with other medicines?

Tell your doctor about all of the medicines that you or your child takes including prescription and nonprescription medicines, vitamins, and herbal supplements. Daytrana™ and some medicines may interact

with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while using Daytrana™.

Your doctor will decide whether Daytrana™ can be used with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- cold or allergy medicines that contain decongestants

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while using Daytrana™ without talking to your doctor first.

How should Daytrana™ be used?

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 or your child's body and cause serious side effects.

See the complete instructions for applying Daytrana™ at the end of this Medication Guide.

- **Use Daytrana™ exactly as prescribed. Daytrana™ comes in four different size (strength) patches.** Your doctor may adjust the dose until it is right for you or your child.
- From time to time, your doctor may stop Daytrana™ treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while using Daytrana™. Children should have their height and weight checked often while using Daytrana™. Daytrana™ treatment may be stopped if a problem is found during these check-ups.
- **If you or your child uses too much Daytrana™ or overdoses, remove all patches and call your doctor or poison control center right away or get emergency treatment.**

What are possible side effects of Daytrana™?

Skin reactions including skin irritation and allergic skin rash can happen with Daytrana™. Skin redness or itching at the application site is common. You can keep using Daytrana™ if this happens. Stop using Daytrana™ and see your doctor right away if swelling, bumps, or blisters happen at or around the application site. You may have a skin allergy to Daytrana™. People that have skin allergies with Daytrana™ may develop an allergy to all medicines that contain methylphenidate, even those taken by mouth.

See “**What is the most important information I should know about Daytrana™**,” for information on reported heart and mental problems.

Other serious side effects include:

- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- eyesight changes or blurred vision

Common side effects include:

- nausea
- decreased appetite
- vomiting
- decreased weight
- trouble sleeping
- tics
- mood swings

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

How should I store Daytrana™?

- Store Daytrana™ in a safe place at room temperature, 59 to 86° F (15 to 30° C). Keep Daytrana™ patches in their unopened pouches until ready to use.
- Once a tray of patches has been opened, use or discard the patches within 2 months.
- Do not store Daytrana™ in the refrigerator or freezer.
- **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 condition. 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 was written for healthcare professionals. For more information about Daytrana™ call 1-800-828-2088 or visit www.daytrana.com.

Skin care information about Daytrana™

Skin redness or itching is common with Daytrana™, and small bumps on the skin may also occur in some patients. If you have any swelling or blistering, the patch should not be worn and you should consult your doctor. Do not apply any medicine, cream, or lotion on the skin at the Daytrana patch site before applying the patch, since this might affect how the patch sticks to the skin and how the medicine is absorbed from the patch.

INSTRUCTIONS FOR APPLYING DAYTRANA™ (methylphenidate transdermal system)

1. USING THE ADMINISTRATION CHART

Each carton of Daytrana™ contains an administration chart to help parents or caregivers keep track of when the patch is applied each morning, when it is removed and the method of disposal used. Daytrana™ should be worn for about 9 hours.

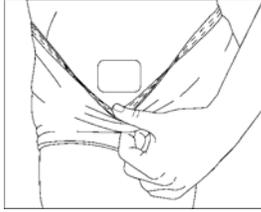
To use the administration chart, follow these instructions:

- Each day, when a new patch is applied, write down the date and time that the patch is applied.
- Use the timetable below to calculate when to remove the patch. For example, if the patch is applied at 6:00 a.m., it should be removed at 3:00 p.m. later the same day.
- After removing and disposing of the patch, write down the time the patch was removed and how it was disposed.
- If the applied patch is missing, ask the child when and how the patch came off.

Timetable for 9-Hour Daytrana™ Application and Removal

If you applied the patch at:	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 the hip area. Avoid the waistline, since clothing may cause the patch to rub off.
- When applying a new patch the next morning, use the child's other hip. Make sure there is no irritation at the site where the patch is going to be applied.

3. BEFORE YOU APPLY DAYTRANA™

The patch should separate easily from the protective liner. Do not use the patch if the protective liner is difficult to remove.

Look at the patch to make sure it is not damaged or defective in any way. After the protective liner is removed, there should not be any adhesive (glue) sticking to the liner.

If the patch is damaged, or you have problems removing it from the liner, discard the patch according to the instructions provided below (see How to Remove and Discard Daytrana™), and apply a new one to the child's skin.

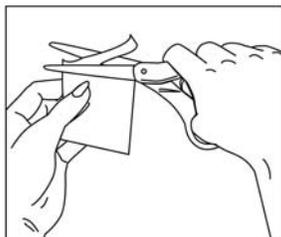
Do not use patches that have been stored in the refrigerator or freezer.

Make sure the child's skin is:

- Clean (freshly washed), dry, and cool.
- Free of any powder, oil, or lotion.
- Free of cuts and irritation (rashes, inflammation, redness, or other skin problems).

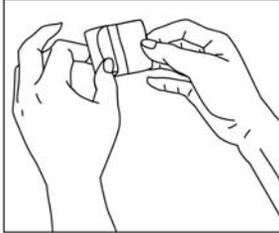
4. HOW TO APPLY DAYTRANA™

- Open the tray containing Daytrana™ and discard the small packet (drying agent) included in the tray.
- 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.**
- Remove the patch from the pouch.



- **Apply the patch right away after removing from pouch.**
- Hold the patch with the rigid protective liner facing you – **the word Daytrana™ will appear backwards.**

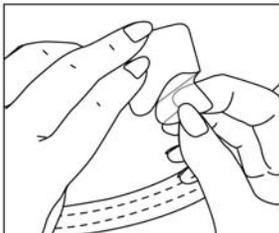
- **Gently** bend the patch along the faint line and **slowly peel** half the liner, which covers the sticky surface of the patch.
- Avoid touching the sticky side of the patch with your fingers.
- If you accidentally touch the sticky side of the patch, apply the patch, then wash your hands right away so that you do not absorb the medicine.



- 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.
- Press the sticky side of the patch firmly into place and smooth it down.



- While still holding the sticky side down, gently fold back the other half of the patch.
- Grasp an edge of the remaining protective liner and **slowly peel** it off.



- Avoid touching the sticky side of the patch with your fingers.
- If you do touch the sticky side of the patch, wash your hands immediately after application.



- **Press the entire patch firmly into place with the palm of your hand over the patch, for about 30 seconds.**

- Make sure that the patch firmly sticks to the child's skin.
- Go over the edges with your fingers to assure good contact around the patch.
- Wash your hands after applying the patch.
- After the patch is applied, record the time on the administration chart on each carton, and use the timetable to calculate what time the patch should be removed.

PLEASE NOTE:

- **Contact with water while bathing, swimming, or showering can make the patch not stick well or make it fall off. If a patch falls off, do not touch the sticky side of the patch with your fingers. A new patch may be applied to a different area of the same hip. Patches that fall off should not be re-applied. Do not use bandages, tape, or other household adhesives (glue) to hold the patch on the skin. If a new patch is applied, remove it 9 hours after the first patch for that day was applied. Always wash your hands after handling a patch.**
- If you forget to apply a patch in the morning, you may do so later in the day. However, you should remove the child's patch at the usual time of day to reduce the chance of later day side effects. You can use the timetable above to know when to remove the patch.
- **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 or your child's body and cause serious side effects.**

5. **HOW TO REMOVE AND DISCARD DAYTRANA™**

- When you remove the patch, peel it off slowly. If needed, patch removal may be helped by gently applying an oil-based product (petroleum jelly, olive oil, or mineral oil) to the patch edges, gently working the oil underneath the patch edges. If any adhesive (glue) remains on the skin after the patch is removed, an oil based product may be applied to patch sites in an effort to gently loosen and remove any leftover adhesive that remains following patch removal.
- In the unlikely event that a patch remains tightly adhered despite these measures, ask your doctor or pharmacist about what to do for this problem.
- Fold the used Daytrana™ patch in half and press firmly so that the sticky side sticks to itself. **Flush the used patch down the toilet or dispose of it in a lidded container right away.**
- Do not flush the pouches or the protective liners down the toilet. These items should be thrown away in a lidded container.
- If any sticky material (adhesive) remains on the child's skin after removing the patch, gently rub the area with oil or lotion to remove the adhesive from the skin.
- Wash your hands after handling the patch.
- After the patch is removed and disposed of, record this time on the administration chart.

UNUSED PATCHES

- Throw away any unused Daytrana™ patches that are left over from the prescription as soon as they are no longer needed. Remove the leftover patches from their protective pouches and remove the protective liners. **Fold the patches in half with the sticky sides together, and flush the patches down the toilet or dispose of them in a lidded container.**

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

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