

MEDICATION GUIDE
DYANAVEL XR (dī-an-uh-vel)
(amphetamine)
extended-release oral suspension, CII

What is the most important information I should know about DYANAVEL XR?

DYANAVEL XR can cause serious side effects, including:

- **Abuse and dependence.** DYANAVEL XR, other amphetamine containing medicines, and methylphenidate have a high chance for abuse and can cause physical and psychological dependence. Your healthcare provider should check you or your child for signs of abuse and dependence before, and during, treatment with DYANAVEL XR.
 - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
 - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- **Heart-related problems, including:**
 - sudden death, stroke and heart attack in adults
 - sudden death in children and adolescents who have heart problems or heart defects
 - increased blood pressure and heart rate

Your healthcare provider should check you or your child carefully for heart problems before starting DYANAVEL XR. Tell your healthcare provider if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your healthcare provider should check your or your child's blood pressure and heart rate regularly during treatment with DYANAVEL XR.

Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking DYANAVEL XR.

- **Mental (psychiatric) problems, including:**
 - new or worse behavior and thought problems
 - new or worse bipolar illness
 - new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms

Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems while taking DYANAVEL XR, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is DYANAVEL XR?

DYANAVEL XR is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). DYANAVEL XR may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if DYANAVEL XR is safe and effective in children under 6 years of age.

DYANAVEL XR is a federally controlled substance (CII) because it contains amphetamine that can be a target for people who abuse prescription medicines or street drugs. Keep DYANAVEL XR in a safe place to protect it from theft. Never give your DYANAVEL XR to anyone else, because it may cause death or harm them. Selling or giving away DYANAVEL XR may harm others and is against the law.

Do not take DYANAVEL XR if you or your child are:

- allergic to amphetamine or any of the ingredients in DYANAVEL XR. See the end of this Medication Guide for a complete list of ingredients in DYANAVEL XR.
- taking or have taken within the past 14 days a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

Before taking DYANAVEL XR tell your healthcare provider about all medical conditions, including if you or your child:

- have heart problems, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression
- have circulation problems in fingers and toes
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if DYANAVEL XR will harm your unborn baby.
- are breastfeeding or plan to breastfeed. DYANAVEL XR passes into breast milk. You should not breastfeed while you are taking DYANAVEL XR.

Tell your healthcare provider about all of the medicines that you or your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

DYANAVEL XR 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 taking DYANAVEL XR.

Especially tell your healthcare provider if you or your child take medicines used to treat depression including MAOIs.

Your healthcare provider will decide whether DYANAVEL XR can be taken with other medicines. **Do not start any new medicine while taking DYANAVEL XR without talking to your healthcare provider first.**

How should I take DYANAVEL XR?

See the detailed “Instructions for Use” for information on how to give a dose of DYANAVEL XR.

- Take DYANAVEL XR exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take DYANAVEL XR 1 time each day in the morning.
- DYANAVEL XR can be taken with or without food.
- Your healthcare provider may sometimes stop DYANAVEL XR treatment for a while to check ADHD symptoms.
- If you or your child take(s) too much DYANAVEL XR, call your healthcare provider or poison control center, or go to the nearest hospital emergency room right away. In case of poisoning call your poison control center at 1-800-222-1222.

What should I avoid while taking DYANAVEL XR?

- drinking alcohol

What are possible side effects of DYANAVEL XR?

DYANAVEL XR can cause serious side effects, including:

- See “**What is the most important information I should know about DYANAVEL XR?**”
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often while taking DYANAVEL XR.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud’s phenomenon).** Signs and symptoms may include:
 - fingers or toes may feel numb, cool, painful

- fingers or toes may change color from pale, to blue, to red

Tell your healthcare provider if you or your child have numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call your healthcare provider right away if you or your child have any signs of unexplained wounds appearing on fingers or toes while taking DYANAVEL XR.

The most common side effects of amphetamine products include:

- dry mouth
- decreased appetite
- weight loss
- stomach pain
- nausea
- trouble sleeping
- restlessness
- extreme mood changes
- dizziness
- increased heart rate

These are not all the possible side effects of DYANAVEL XR.

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 DYANAVEL XR?

- Store DYANAVEL XR at room temperature between 68°F to 77°F (20°C to 25°C).
- Store DYANAVEL XR in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired DYANAVEL XR by a medicine take-back program at authorized collection sites such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix DYANAVEL XR with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away DYANAVEL XR in the household trash.

Keep DYANAVEL XR and all medicines out of the reach of children.

General information about the safe and effective use of DYANAVEL XR

Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not use DYANAVEL XR for a condition for which it has not been prescribed. Do not give DYANAVEL XR to other people, even if they have the same condition. It may harm them and it is against the law. You can ask your healthcare provider or pharmacist for information about DYANAVEL XR that was written for health professionals.

What are the ingredients in DYANAVEL XR?

Active Ingredient: amphetamine

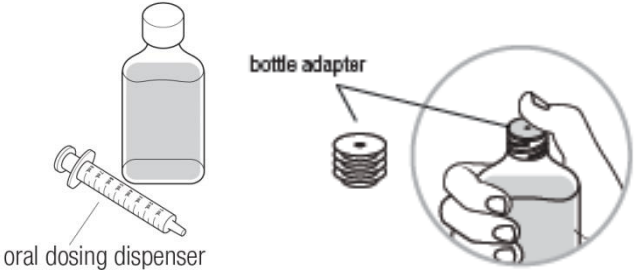

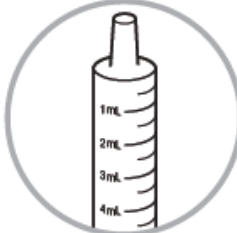
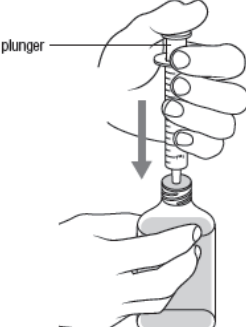
Inactive Ingredients: anhydrous citric acid, bubblegum flavor, glycerin, methylparaben, modified food starch, polysorbate 80, povidone, polyvinyl acetate, propylparaben, sodium lauryl sulfate, sodium polystyrene sulfonate, sucralose, triacetin and xanthan gum

Manufactured by: **Tris Pharma, Inc.**, Monmouth Junction, NJ 08852

For more information about DYANAVEL XR go to www.dyanavelxr.com or call 1-732-940-0358.

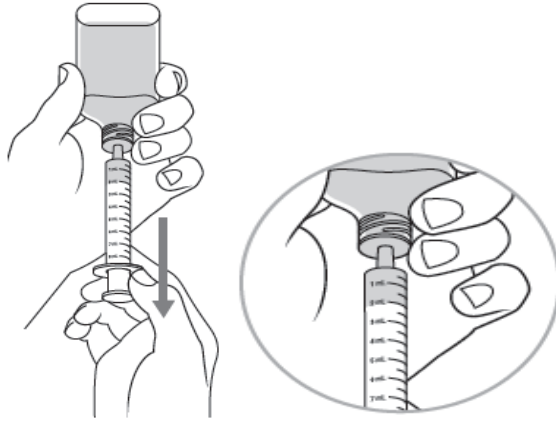
Instructions for Use
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(amphetamine)
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Read this Instructions for Use before taking DYANAVEL XR and each time you get a refill. There may be new information. This leaflet does not take the place of talking with the healthcare provider about your or your child's medical condition or treatment.

<p>Step 1:</p> <ul style="list-style-type: none">• Check the DYANAVEL XR bottle to make sure that the bottle adapter has been inserted into the bottle by the pharmacist. Do not remove the bottle adapter.• Check to make sure your pharmacist has given you an oral dosing dispenser.• Tell your pharmacist if an oral dosing dispenser is not provided or the bottle adapter is missing from the neck of the bottle.	 <p>oral dosing dispenser</p> <p>bottle adapter</p>
<p>Step 2:</p> <ul style="list-style-type: none">• Shake the bottle well (up and down).	
<p>Step 3:</p> <ul style="list-style-type: none">• Check the DYANAVEL XR oral dosing dispenser to find the right dose in milliliters (mL) that you or your child's healthcare provider has prescribed.	
<p>Step 4:</p> <ul style="list-style-type: none">• Place the DYANAVEL XR bottle upright and insert tip of the oral dosing dispenser into the bottle. <p>Step 5:</p> <ul style="list-style-type: none">• Push the plunger all the way down.	 <p>plunger</p>

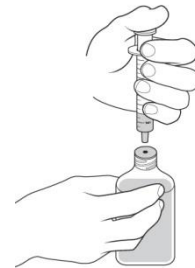
Step 6:

- With the oral dosing dispenser in place, hold the DYANAVEL XR bottle with 1 hand and turn the bottle upside down. Pull the plunger down until the white end reaches the number of mLs you need for the prescribed dose.



Step 7:

- Turn the bottle over and place upright on a counter top, then remove the oral dosing dispenser from the bottle adapter.



Step 8:

- Place the tip of the oral dosing dispenser into you or your child's mouth. Point the tip toward the cheek and slowly push the plunger all the way down to give the DYANAVEL XR dose.



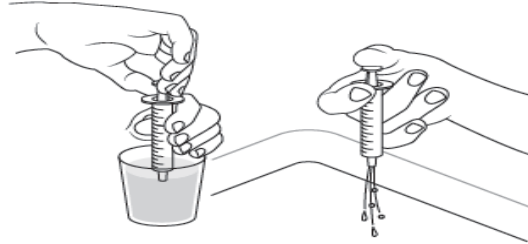
Step 9:

- Put the DYANAVEL XR cap back on the bottle and close tightly.



Step 10:

- Clean the oral dosing dispenser after each use by placing in the dishwasher, or by rinsing with tap water.

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This Instructions for Use has been approved by the U.S. Food and Drug Administration

Approved: 05/2017

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