

**MEDICATION GUIDE**  
**DUVYZAT™ (doo' vi zat)**  
**(givinostat)**  
**oral suspension**

**What is the most important information I should know about DUVYZAT?**

**DUVYZAT can cause serious side effects including:**

- **Low platelet counts in your blood (thrombocytopenia).** Platelets are important for blood clotting, and a decrease in their numbers can lead to an increased risk of bleeding or bruising. Your healthcare provider will check your blood count before you start DUVYZAT and regularly during treatment for any signs of thrombocytopenia. Call your healthcare provider right away if you notice any unusual bleeding or small red or purple spots on the skin called petechiae. Your healthcare provider may change your dose of DUVYZAT if your blood platelet counts continue to be low or may stop your treatment with DUVYZAT.
- **Increased levels of fat (triglycerides) in your blood.** You may not have any symptoms, so your healthcare provider will do blood tests before you start DUVYZAT and regularly during treatment to check your triglyceride levels. Your healthcare provider may change your dose of DUVYZAT if your triglyceride levels continue to be high or may stop your treatment with DUVYZAT.
- **Frequent watery loose stools (diarrhea) and vomiting.** DUVYZAT can cause vomiting and moderate to severe diarrhea. If diarrhea occurs, you should keep track of the frequency and severity of your diarrhea symptoms, drink plenty of fluids, and contact your healthcare provider. Your healthcare provider may change your dose of DUVYZAT if the diarrhea cannot be managed or does not go away. Your healthcare provider may also stop your treatment with DUVYZAT.

**What is DUVYZAT?**

DUVYZAT is a prescription medicine that is used for the treatment of Duchenne muscular dystrophy (DMD) in people 6 years of age and older.

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

**Before taking DUVYZAT, tell your healthcare provider about all of your medical conditions, including if you:**

- have any heart problems or if you take any medicines that could increase your chance for irregular heart rhythms.
- have any bleeding problems.

**Tell your healthcare provider about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking DUVYZAT with certain other medicines may affect each other. Taking DUVYZAT with other medicines can cause serious side effects. Do not start or stop other medicines without talking to your healthcare provider.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I take DUVYZAT?**

- See the **Instructions for Use** that came with your DUVYZAT medicine for detailed instructions on how to take DUVYZAT the right way.
- Take DUVYZAT by mouth with food.
- Take DUVYZAT exactly as prescribed. Your healthcare provider will tell you how much DUVYZAT to take and when to take it.
- Your healthcare provider may change your dose of DUVYZAT if needed. Do not change your dose of DUVYZAT without talking to your healthcare provider.
- Shake the bottle for at least 30 seconds by continuously turning the bottle up and down. Stop when the DUVYZAT suspension looks the same throughout.
- Take the prescribed dose of DUVYZAT by mouth (orally) using the oral syringe that came with your DUVYZAT medicine. Do not throw away the oral syringe.
- DUVYZAT should not be mixed with water or other liquids.
- If you miss a dose of DUVYZAT, skip the missed dose and take your next dose of DUVYZAT as scheduled.

**What are the possible side effects of DUVYZAT?**

**DUVYZAT can cause serious side effects, including:**

- see **“What is the most important information I should know about DUVYZAT?”**
- **changes in the electrical activity of your heart called QT Prolongation.** QT Prolongation can increase the risk of developing a type of irregular heart rhythm known as Torsades de Pointes. Call your healthcare provider right away if you feel faint, have an irregular heartbeat, feel dizzy, or lose consciousness.

**The most common side effects of DUVYZAT include:**

- |                                   |                                     |
|-----------------------------------|-------------------------------------|
| • loose, watery stools (diarrhea) | • low platelet counts in the blood  |
| • nausea                          | • increased fat levels in the blood |

- vomiting
- stomach (abdominal) pain
- fever

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

These are not all of the possible side effects of DUVYZAT. For more information, ask your healthcare provider or pharmacist.

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

**General information about the safe and effective use of DUVYZAT.**

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

You can ask your pharmacist or healthcare provider for information about DUVYZAT that is written for healthcare professionals.

**What are the ingredients in DUVYZAT?**

**Active ingredient:** givinostat

**Inactive ingredients:** cream flavor, glycerin, non-crystallizing sorbitol solution, peach flavor, polysorbate 20, purified water, saccharin sodium, sodium benzoate, sodium hydroxide, tartaric acid, and tragacanth.

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ITF Therapeutics, LLC  
Concord, MA 01742

For more information, go to [www.DUVYZAT.com](http://www.DUVYZAT.com) or call 1-833-582-4312

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

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