



The first nonsteroidal treatment option for patients 6 years and older with Duchenne muscular dystrophy (DMD), no matter the genetic mutation

DUVYZAT works differently than other DMD medicines to help protect from muscle loss.

**CLINICALLY PROVEN
TO MAINTAIN MUSCLE
FUNCTION LONGER
THAN STEROIDS ALONE**

**Ask your healthcare
provider if DUVYZAT is
right for you.**



Indication

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.

Please see full Important Safety Information on pages 2-3.

Please visit [DUVYZAT.com](https://www.duvyzat.com) to view the full Prescribing Information and Medication Guide.

Indication and Important Safety Information

What is DUVYZAT?

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Important Safety Information

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

- **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.

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.



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 included diarrhea, nausea, vomiting, stomach pain, low platelet counts in the blood, increased fat level in the blood and fever.

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.

Please visit DUVYZAT.com to view the full Prescribing Information and Medication Guide.



DUVYZAT: A UNIQUE, ONE-OF-A-KIND DMD TREATMENT

DUVYZAT is not a steroid. As a histone deacetylase (HDAC) inhibitor, DUVYZAT works differently than other types of DMD medicines to address the issues caused by lack of dystrophin.

While the exact process is unknown, it is thought that HDAC inhibition helps:



Reduce inflammation



Increase muscle repair



Slow muscle loss

DUVYZAT is not limited to a specific type of genetic mutation, which means that eligible patients with DMD 6 years and older can take DUVYZAT.

DUVYZAT WAS STUDIED IN ONE OF THE LARGEST DMD CLINICAL TRIALS IN HISTORY: EPIDYS



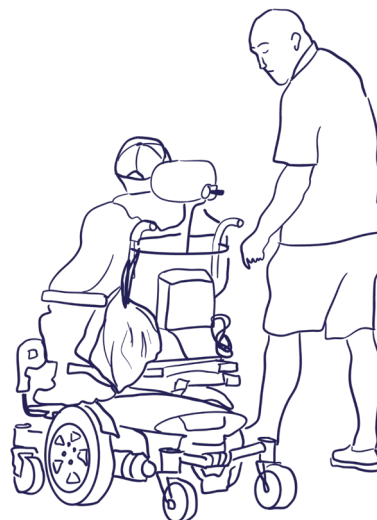
18 months long



Participants received steroids along with either DUVYZAT or placebo



Included 179 participants with a wide range of genetic subtypes of DMD



RESEARCHERS LOOKED AT:

- How fast participants could climb 4 stairs before and after 18 months of using DUVYZAT, compared to placebo
- Participants' mobility, as measured by the North Star Ambulatory Assessment (NSAA)
- How much muscle was replaced by fat, a measurement of muscle loss



The NSAA is a test that helps healthcare providers understand how well children with DMD can move and do daily activities by watching them perform specific tasks.

Select Safety Information

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CLINICALLY PROVEN TO MAINTAIN MUSCLE FUNCTION LONGER THAN STEROIDS + PLACEBO

In the EPIDYS clinical trial, DUVYZAT + steroids was more effective at slowing down the worsening of DMD symptoms than steroids + placebo.



DUVYZAT helped maintain muscle strength and motor function **about 40%** better than using steroids + placebo*

*As measured by mean change in time from baseline to 18 months of 4-stair climb in DUVYZAT vs placebo.

- After 18 months, participants taking DUVYZAT generally saw less muscle loss than those who took placebo
- Using the NSAA, trial participants taking DUVYZAT generally saw slower decline in measures of motor function than those who took placebo

Please see full Prescribing Information and Medication Guide.



THE SAFETY OF DUVYZAT HAS BEEN WELL STUDIED

- In the EPIDYS clinical trial, the most common side effects were diarrhea, abdominal pain, low blood platelet counts, nausea/vomiting, high triglyceride levels, fever, and muscle aches
- Your healthcare provider will monitor for changes in blood measurements
- If side effects occur, your healthcare provider can adjust the dose to help reduce them



Only 2% of participants in the clinical trial stopped taking DUVYZAT due to side effects.

Talk with your healthcare provider if side effects occur.

Select Safety Information

What is the most important information I should know about DUVYZAT? (cont'd)

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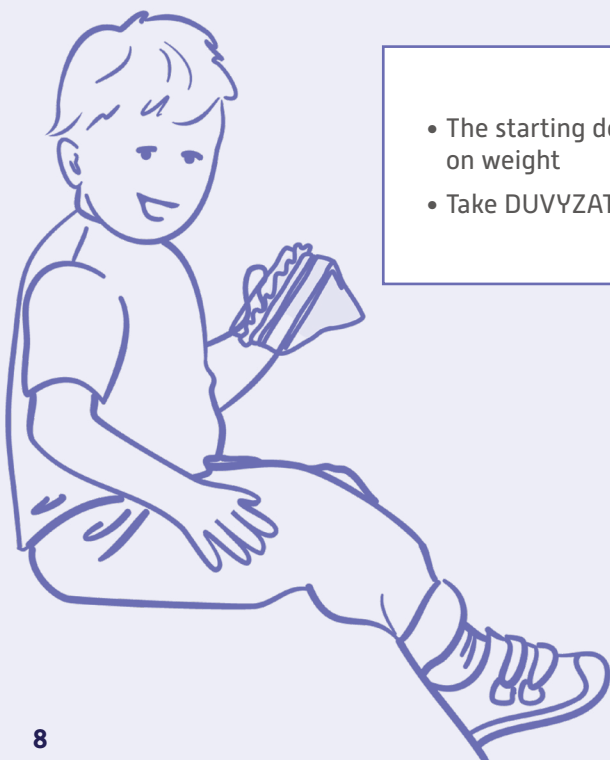
TAKING DUVYZAT

DUVYZAT is a liquid medicine that can be taken at home, twice a day.



DUVYZAT should be taken once in the morning and once at night to establish a daily routine.

- The starting dose for DUVYZAT is based on weight
- Take DUVYZAT with food



WHAT TO EXPECT WHEN STARTING DUVYZAT

Before starting DUVYZAT, your healthcare provider will perform:

- Tests to look at blood counts (platelets and triglyceride levels)
- An electrocardiogram (if there is an underlying heart condition or the individual with DMD is taking other medications that affect heart rhythm)



Your healthcare provider will monitor blood counts every 2 weeks for the first 2 months of treatment, then monthly for the first 3 months, and every 3 months afterward.

Select Safety Information

What is the most important information I should know about DUVYZAT? (cont'd)

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DEDICATED SUPPORT TO HELP MAKE IT EASIER TO ACCESS THERAPY

ITF ARC offers support that helps make insurance coverage navigation easier, helps address financial concerns, and encourages adherence to therapy.

Here are some of the ways we may be able to help:



Insurance navigation:

- Insurance coverage benefits verification
- Prior authorization and appeal support, as needed
- Medication deliveries to home or preferred address



Education and adherence:

- Personalized pharmacist support
- Translation services available as needed
- Educational materials about DMD and how DUVYZAT™ (givinostat) may be able to help
- Coordination between families and healthcare providers, including refill reminders

ITF ARC provides a variety of financial support options:



Copay Program



Patient Assistance Program



Temporary supply programs

TIPS AND BEST PRACTICES FOR ITF ARC

If you and your healthcare provider decide that DUVYZAT is right for you, ITF ARC is here to help.

To get the most during treatment with DUVYZAT, keep the following tips in mind:



As part of the prescription process, complete the authorization form to be enrolled in ITF ARC



Provide your mobile number for ease of communication and important updates



Calls from pharmacies can often appear as unknown numbers, so be sure to answer or return calls as needed so the pharmacy can quickly address any issues



Visit duvyzat.com/ITFARC for more information.

Have questions?

Contact a case manager at ITF ARC.

1-855-4 ITF ARC (855-448-3272)
8 AM-8 PM ET, Monday-Friday

Each patient's eligibility for access programs is evaluated on an individual case-by-case basis. To be eligible, use of DUVYZAT must be consistent with the FDA-approved indication. All programs are designed to comply with state and federal regulations. All programs may be modified or discontinued at any time for any reason, including eligibility criteria, state and federal laws, and program availability.

Restrictions apply. See full restrictions for ITF Therapeutics' Copay Program, Patient Assistance Program, and temporary supply programs at duvyzat.com/ITFARC.



IS DUVYZAT RIGHT FOR YOU OR YOUR LOVED ONE?

In a clinical trial, DUVYZAT + steroids was more effective at slowing down the worsening of DMD symptoms than steroids + placebo.

If you or your loved one answer “yes” to all of the questions below, talk with your healthcare provider about DUVYZAT:

- ☒ Are you diagnosed with DMD?
- ☒ Are you 6 years of age or older?
- ☒ Are you currently seeking a nonsteroidal treatment option that does not require a specific genetic mutation?



Visit duvyzat.com to learn more and sign up for updates.

Select Safety Information

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