# A CAREGIVER'S GUIDE

## to navigating Duchenne muscular dystrophy with DUVYZAT

Duvyzat® (givinostat)

Grant, taking DUVYZAT since 2025, and his parents, Leslie and Clint.

### Indication

**What is DUVYZAT?**

DUVYZAT is a prescription medicine 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 age 6.

### 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, so having fewer can increase your risk of bleeding or bruising. Your doctor will check your blood count before you start DUVYZAT and regularly during treatment for signs of thrombocytopenia. Call your doctor right away if you notice unusual bleeding or small red or purple spots on the skin.

**Please see full Important Safety Information on pages 16 and 17.**
**Please see full Prescribing Information and Medication Guide.**

# A note from Leslie, caregiver to her son Grant, who is living with Duchenne

Dear Caregiver,

My name is Leslie and I'm a Duchenne mom and caregiver to my 15-year-old son, Grant. Grant has been taking DUVYZAT for 2 years, and it's the first Duchenne-specific treatment he has been eligible to receive since his diagnosis in 2017. DUVYZAT is not a cure, but knowing that we have a treatment that may help has given our family a renewed sense of hope.

While starting a new treatment can feel hopeful, for me it was also overwhelming. A new treatment brings new routines, possible side effects to watch for and manage, and a schedule of lab monitoring that can feel like one more responsibility added to an already full plate.

One of the things that felt most intimidating to me was the lab schedule. When Grant first started treatment, the appointments were frequent, and it seemed like we were constantly looking ahead to the next one. But, before long, for us, the lab visits became less frequent and gradually became part of our routine. I found it helpful to set reminders on my phone so I didn't have to rely on memory for when we needed to get them done.

It's also okay to acknowledge your fears. Be gentle with yourself as you navigate this journey.

Caregiving doesn't follow a straight line. Some days you might feel strong. Other days you might feel exhausted. Both are normal. Give yourself permission to feel what you need to feel and remember that you're not alone.

Your care team, the ITF ARC patient support program, your specialty pharmacy team (PANTHERx), and the larger Duchenne community are all part of your support system. This guide was shaped by the experiences of caregivers who have walked this path before you. My hope is that you'll find practical ideas, encouragement, and reassurance that you can come back to whenever needed.

Over the years, I've learned that when I stay present—when I stop comparing our life to what I expected or worrying about what may come next—I find so much joy in the family I have today. Wherever you are in this journey, I hope you can find something in this guide to offer support.

With love,

## Important Safety Information (cont'd)

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

- **Increased levels of fat (triglycerides) in your blood.** You may not have any symptoms, so your doctor will do blood tests before you start DUVYZAT and regularly during treatment to check your triglyceride levels.

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# What you'll find in this guide

**This brochure was created for caregivers with input from real caregivers and is a resource you can hold on to and return to over time. In it, you'll find information about:**


Starting treatment ..... ***Page 4***

Navigating side effects ..... ***Page 8***

Planning for the future ..... ***Pages 10–12***

Real caregiver stories ..... ***Page 13***

Tips and resources ..... ***Pages 14, 15, and 18***

Grant, taking DUVYZAT since 2025, and his mom, Leslie.

*Duchenne brings challenges. It brings uncertainty, disappointment, and moments of fear. But it also brings incredible love. It teaches perspective. It reveals strength you never knew you had. It deepens gratitude for ordinary moments that once seemed small.*

*– Leslie, real caregiver to Grant, pictured on the right*

## Important Safety Information (cont'd)

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

- **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 doctor.
- If thrombocytopenia, increased triglycerides, or diarrhea cannot be managed, your doctor may change your dose or stop your treatment with DUVYZAT, if needed.


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# Initial support

The beginning of the caregiver journey can bring a lot at once: new information, appointments, treatment decisions, and questions you may not have answers to yet. By moving at a pace that feels right for you and leaning on your care team when needed, you can continue supporting your loved one while also taking care of yourself.

## Care team interactions

As you get started on DUVYZAT, it may be helpful to provide your care team with important information to get the most out of every appointment.

**Use the list below to prepare or create your own reusable list or fact sheet that includes:**

Current prescriptions or medications, including doses and how often they're taken:

Relevant medical history, including allergies and previous surgeries or hospitalizations:

Treating physicians and contact information:

Pharmacy information:

Other information to include:

**Note that these are suggestions only.** While the above may serve as a helpful starting point, your care team can help you decide which details are most important to bring to each appointment.

### Important Safety Information (cont'd)

**Before taking DUVYZAT, tell your doctor about all of your medical conditions, including:**

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

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# What to expect when starting DUVYZAT

## Your DUVYZAT prescription

Once DUVYZAT has been prescribed, your loved one's healthcare provider will complete the required patient start form and help enroll you in ITF ARC (which stands for "Access, Resources, Care"), a support program for those taking DUVYZAT.

- **Insurance and access:** ITF ARC can help you navigate insurance and offers a Patient Assistance Program for eligible patients who do not have insurance or whose insurance does not cover their prescription
- **Specialty pharmacy (PANTHERx®):** You will receive a welcome call from the pharmacy to answer questions you may have and coordinate delivery of your prescription
- **Medication delivery:** Your medication will be delivered to your home or preferred address. The pharmacy will call with refill reminders each month. Communications may be more frequent at the start of treatment

## Dedicated support through ITF ARC

ITF ARC offers personalized support to help you and your loved one navigate treatment with DUVYZAT.

***EXPLORE SUPPORT DESIGNED FOR PATIENTS AND CAREGIVERS.***

*If you receive an insurance denial, know that you have options and you don't have to navigate the process alone. Your clinic can provide supporting medical documentation when appropriate. The ITF ARC patient support program and other Duchenne community organizations are valuable resources for education, guidance, and support as you work through an insurance appeal.*

*– Leslie, real caregiver to someone living with Duchenne*

### Important Safety Information (cont'd)

**Before taking DUVYZAT, tell your doctor about all of your medical conditions, including (cont'd):**

- any bleeding problems.

**Tell your doctor 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 doctor.

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# What to expect when starting DUVYZAT (cont'd)

## Taking DUVYZAT

DUVYZAT is a liquid medicine taken by mouth twice a day. Dosing is based on weight. Ask your loved one's healthcare provider how to measure the prescribed dose of DUVYZAT and refer to the accompanying Instructions for Use. It's important to take DUVYZAT exactly as prescribed by your loved one's healthcare provider.

- If a dose is missed, skip the missed dose and take the next dose of DUVYZAT as scheduled

## Initial testing

After starting DUVYZAT, your loved one's healthcare provider will perform blood tests to check levels of platelets (tiny cell fragments that help blood clot) and triglycerides (a type of fat in your blood). A heart test called an electrocardiogram, or EKG, may also be required for those who have an underlying heart condition or who are taking medicines that might affect heart rhythm.

## Ongoing monitoring

After starting DUVYZAT, your loved one's healthcare provider will closely monitor their health through regular blood tests. **These tests are more frequent at the beginning of treatment and may become less frequent over time.** Talk to your loved one's healthcare provider for help coordinating lab appointments.

***FOR MORE INFORMATION, INCLUDING THE FULL MONITORING SCHEDULE FOR DUVYZAT, SEE THE MONITORING BROCHURE.***

### Important Safety Information (cont'd)

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

- **DUVYZAT can cause serious side effects, including** 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 doctor right away if you feel faint, have an irregular heartbeat, feel dizzy, or lose consciousness. **See the section titled "What is the most important information I should know about DUVYZAT?" for more information about side effects.**

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## Planning for monitoring appointments

Feeling anxious about blood draws is common. If your loved one is feeling nervous, let the nurse or phlebotomist know before the appointment begins. They may be able to help make the experience feel more comfortable and predictable.

**Here are some additional tips to consider ahead of blood draws:**

- Bring a video game, phone, tablet, book, or other distraction
- Plan a small reward or treat for after the appointment
- Give your loved one a choice when possible, such as which arm to use or what color bandage they want afterward
- Ask whether a pediatric phlebotomist is available
- Talk to your loved one's healthcare provider about in-home monitoring through ITF ARC

## Checklist for the first 30 days

- [ ] If your loved one's healthcare provider hasn't already done so, ask them to complete the patient start form, which includes enrollment in ITF ARC
- [ ] Save the pharmacy's number in your phone
- [ ] Contact your loved one's healthcare provider about scheduling lab appointments before taking the first dose of DUVYZAT

**What's on your list? Add your own notes or to-do's below:**

- [ ] _____
- [ ] _____
- [ ] _____
- [ ] _____

### Important Safety Information (cont'd)

**What are the possible side effects of DUVYZAT? (cont'd)**

The most common side effects (occurring in >5% of DUVYZAT-treated patients) included diarrhea, abdominal pain, low platelet levels, nausea/vomiting, high triglyceride levels, elevated temperature/fever, muscle aches, rash, joint pain, fatigue, constipation and decreased appetite.

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# Navigating side effects

As with any medicine, side effects may occur with DUVYZAT. After starting treatment, make note of any changes and report them to your loved one's healthcare provider. They may adjust the dosage to help manage side effects.

**Most common side effects in the phase 3 clinical trial of 179 participants*,†**

**Diarrhea (37%), abdominal pain (34%), low platelet levels (33%), nausea/vomiting (32%), high triglyceride levels (23%), elevated temperature/fever (13%), muscle aches (9%), rash (9%), joint pain (8%), fatigue (8%), constipation (7%), and decreased appetite (7%)**

*DUVYZAT was studied in EPIDYS, an 18-month clinical trial that measured whether DUVYZAT + steroids more effectively preserved muscle strength and function than steroids alone (placebo).

†Experienced by more than 5% of the participants in the clinical trial.

***GET MORE INFORMATION ON TREATMENT WITH DUVYZAT, INCLUDING POSSIBLE SIDE EFFECTS, IN THE DUVYZAT PATIENT BROCHURE.***

## About low platelet counts and increased triglyceride levels

Thrombocytopenia (low platelet counts) and increased triglyceride levels in the blood can occur while on DUVYZAT. Your loved one's healthcare provider will monitor these in blood tests. If changes are detected during monitoring, the dosage of DUVYZAT can be adjusted to help address these side effects.

*Conner did experience low platelets [after starting DUVYZAT]. With careful monitoring and working with our healthcare provider, he was able to resume his normal treatment plan.*

*– Jessica, real caregiver to Conner, pictured on the right*

Conner, taking DUVYZAT since 2024, and his mom, Jessica.

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## About gastrointestinal issues

Diarrhea, abdominal pain, and nausea/vomiting were common side effects in the safety analysis for DUVYZAT. For patients who experienced diarrhea, it usually occurred in the first few weeks of treatment. Most of the time, it was mild and manageable. Very few people had severe cases. Only 1 person needed to pause their treatment due to diarrhea, but no one stopped taking DUVYZAT because of it. If your loved one experiences diarrhea, nausea, or vomiting, talk to their healthcare provider. They may recommend medicines or other steps to help manage these side effects, if needed.

*We've experienced some upset stomach with DUVYZAT, but by working with our physician, we've been able to continue the treatment.*

*– Carlos, real caregiver to 2 boys living with Duchenne*

## Potential side effects to discuss with my loved one's care team

If needed, use the spaces below to make note of any side effects and report them to your loved one's healthcare provider.

| Date | Side effect | Severity |
|---|---|---|
| | | |

Notes

| Date | Side effect | Severity |
|---|---|---|
| | | |

Notes

**Don't stop taking DUVYZAT without first talking to your loved one's healthcare provider. They can adjust the dosage of DUVYZAT to help reduce side effects.**

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# Planning for the future

As your loved one grows, their routines, school experience, and care needs may evolve, too. Some changes can create new opportunities for connection and involvement, while others may feel challenging—especially when support, resources, or next steps aren't always clear. Knowing what may change over time can help your family prepare and adjust. You do not need to plan for everything at once. Your loved one's healthcare providers, school team, and support network can also help guide you today and plan for what's next. **You're not in this alone.**

> *Every time a fear came up, we looked at it, we analyzed it, and we said: Alright, well here's our solution to it. And then we moved on to the next thing.*
>
> *– Carlos, real caregiver to Ethan and Naythan, pictured on the right*

Naythan and Ethan, taking DUVYZAT since 2020, with their sisters and parents, Carlos and Gisela.

## Mobility and independence

In Duchenne, changes like increased fatigue, falls, trouble with stairs, or needing more help with daily tasks may become more common as the disease progresses. These are often signs to talk with physical and/or occupational therapists about equipment, home modifications, or ways to conserve energy. Mobility support can be an adjustment, but it can also help your child stay involved, independent, and connected.

> *Those frequent falls really stopped once Grant started using a mobility chair to help him not get as tired.*
>
> *– Leslie, real caregiver to someone living with Duchenne*

### Important Safety Information (cont'd)

**What are the possible side effects of DUVYZAT? (cont'd)**

These are not all of the possible side effects of DUVYZAT. 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.

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## School, daily routines, and family life

As your loved one's needs change, their Individualized Education Program (IEP) or 504 plan, transportation, classroom setup, and other general accessibility considerations may need to be reevaluated. When possible, people living with Duchenne may benefit from more frequent breaks or a more flexible schedule as time goes on.

*I've always given [his schools] materials on [Duchenne] and they've been very welcoming of it. I've given them some information from [patient advocacy group websites] about students with Duchenne.*

*– Susan, real caregiver to Ryan, pictured below*

Changes in care can affect the whole family, including siblings. When possible, make space for family conversations about what is changing, how everyone is feeling, and ways siblings can stay included in everyday routines, activities, and family time. These kinds of check-ins can be woven into the existing framework of your day: in the car, at the dinner table, or whenever you're all together.

Ryan, taking DUVYZAT since 2019, and his mom, Susan.

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# How your care team may evolve

Some pediatric care providers may continue caring for people living with Duchenne into adulthood, while others may help transition care to adult providers. Talk with your loved one's care team early about what this process may look like.

They may be able to recommend adult specialists, share medical records, and help establish a new care routine. Your care team can also help identify what support may be needed as your loved one's daily life, school, work, independence, or home needs change.

To avoid potential gaps in care, it may also be helpful to review insurance requirements before your loved one enters adulthood, and to ask about:

- Age-related coverage changes
- Medicaid or private insurance renewals
- Prior authorizations
- Equipment coverage
- Any paperwork that may need to be completed ahead of time

## Care changes checklist:

- [ ] Ask your loved one's care team about pediatric-to-adult care planning
- [ ] Confirm adult specialist referrals, if needed
- [ ] Confirm medical record transfers as needed
- [ ] Review insurance renewals, prior authorizations, and age-related coverage changes

## Notes:


### Important Safety Information (cont'd)

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

- **Increased levels of fat (triglycerides) in your blood.** You may not have any symptoms, so your doctor will do blood tests before you start DUVYZAT and regularly during treatment to check your triglyceride levels.

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# Hear from other caregivers

## Meet Conner and his mom, Jessica

Jessica is a teacher, mother, and caregiver to her 15-year-old son, Conner, who lives with Duchenne. Since Conner started DUVYZAT in 2024, Jessica has worked closely with his doctors to support his treatment plan and monitor his progress.

**Diagnosis and symptoms**

Conner was diagnosed with Duchenne when he was 4 years old.

Some of his early signs and symptoms included:

- Change in gait
- Difficulty rising from the floor
- Elevated creatine kinase (CK) levels

**Treatment journey**

Although early conversations with their doctor didn't result in a treatment regimen, Conner was eventually able to join a clinical trial for gene therapy. This was followed by steroids for several years before starting DUVYZAT.

Conner experienced an abnormal platelet count after starting DUVYZAT. His doctor adjusted his dosage until his platelet count returned to normal.

*To other caregivers, remember: In this journey of caring for your child with Duchenne, it's easy to get caught up in the fast-paced life, but don't sweat the small stuff. Take it one day at a time and enjoy the beautiful moments together.*

*– Jessica*

## Stories of Strength

Hear from families navigating life with Duchenne and healthcare providers who share information about treatment with DUVYZAT at our Stories of Strength events.

### Important Safety Information (cont'd)

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

- **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 doctor.

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# Practical tips

These practical tips are meant to help make daily treatment routines, appointments, and planning feel a little more manageable. Use what works for you and ask your care team if you need additional support.

### Build dosing with DUVYZAT into your daily routine

DUVYZAT should be taken with food, so pairing it with a consistent morning and evening routine may help.

### Set reminders

Use phone alarms, calendar alerts, or a shared family reminder to help keep track of twice-daily dosing, refills, labs, and appointments.

### Prepare for lab visits

Bring a comfort item, headphones, or favorite activity. Ask your loved one's care team if any preparation is needed before bloodwork, including fasting.

### Plan for travel

Pack medication, dosing supplies, care team contact information, and any needed documentation in an easy-to-access place. TSA may require a Letter of Medical Necessity if traveling with DUVYZAT. Ask your loved one's healthcare provider for help arranging proper documentation.

### Get ahead of schedule changes

Small changes in plans like dinner out or an overnight away from home can also affect usual routines. Set an extra reminder and pack DUVYZAT, dosing supplies, and any needed food ahead of time.

### Create a "parking lot" note

Write any worries, reminders, or questions in one place instead of trying to hold everything in your head. Use your electronic device, a physical notepad, or even this brochure. It may be helpful to refer to it later.

*Adding in a liquid medication like DUVYZAT was a new routine for our family. It took some time to adjust to a different type of medication and to remember the practical details, like bringing the bottle and a syringe with us when we ate out or traveled.*

*– Leslie, real caregiver to someone living with Duchenne*

## Important Safety Information (cont'd)

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

- If thrombocytopenia, increased triglycerides, or diarrhea cannot be managed, your doctor may change your dose or stop your treatment with DUVYZAT, if needed.

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# Self-care tips

There may be times when the idea of caring for yourself seems impractical, unrealistic, or even selfish. But small acts of self-care can go a long way. The following suggestions were shared by DUVYZAT caregivers and reflect tips they found helpful along the way.

1

**Take a 2-minute reset**
Step into a safe, private space—like the bathroom or your car—and take a few slow breaths. Even a short pause can give you a moment to regroup before the next task. If you're on the go, try it before you enter your destination for a small buffer.

2

**Briefly relieve anxiety**
If you're feeling stressed or anxious, place an ice pack or cold cloth on the back of your neck for a minute or 2, which can offer some brief anxiety relief.

3

**One thing at a time**
Choose one small thing to make your life a little easier: keep lab paperwork in one folder, set a refill reminder, prep a go-bag, or keep wipes/snacks/chargers in the car.

4

**Protect one non-medical moment as a family**
Play a quick game, watch something together, make breakfast a ritual, or pick something interesting to talk about at dinner. This can help siblings feel included and remind the family that not every moment has to revolve around care.

## Important Safety Information (cont'd)

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- any bleeding problems.

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**Tell your doctor 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 doctor.

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

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

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Conner, taking DUVYZAT since 2024.

# Resources

## Communities for caregiver support

Although Duchenne is a rare disease, it boasts a strong network of support.
These organizations equip people living with Duchenne and their loved ones with research, education, advocacy, and community. They provide vital resources such as emotional support, advocacy training, financial assistance, self-care resources, and practical tools to help caregivers manage the significant demands of caregiving.

***LEARN MORE ABOUT SUPPORT ORGANIZATIONS AND EXPLORE AVAILABLE RESOURCES.***

*I would definitely encourage other families to seek out other organizations that are part of the Duchenne community. There's always someone that can help guide you through [a] situation.*

*– Susan, real caregiver to someone living with Duchenne*

### Important Safety Information (cont'd)

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