Duvyzat® ▼
(givinostat)

Q&A

Answers to commonly asked questions for patients prescribed Duvyzat®

This document has been produced for people aged 6 and above who have been prescribed a medication called Duvyzat® (givinostat) for the treatment of Duchenne muscular dystrophy (DMD).

If you have any further questions about your or your child's treatment, please speak with a doctor, nurse, or pharmacist, or any member of the patient's neuromuscular team.

What is Duvyzat® and what is it used for?

Duvyzat® (or givinostat) is an orally administered medicine that works as a histone deacetylase (HDAC) inhibitor. HDAC activity is dysregulated in the muscle cells of patients with Duchenne muscular dystrophy (DMD). DMD is caused by genetic changes that result in a lack of a muscle protein called dystrophin which is needed for muscles to work properly. This abnormality leads to muscle degradation. Duvyzat® can slow down such muscle degradation.

Duvyzat® is used to treat DMD resulting from a genetic defect that affects normal muscle function.

How does Duvyzat® work?

Givinostat is a histone deacetylase (HDAC) inhibitor. It blocks HDAC enzymes which are dysregulated in patients with DMD. It works by targeting pathogenic processes to reduce inflammation and muscle loss associated with DMD.

What is Duvyzat® licensed for in the UK?

Duvyzat® is indicated for the treatment of DMD in patients 6 years of age and older.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at **https://yellowcard.mhra.gov.uk/** or search for MHRA Yellow Card in the Google Play or Apple App Store.

Side effects should also be reported to ITF Pharma Ltd Medical Information on: **0800 098 4040** or **UK.Medical.Information@italfarmacogroup.com** By reporting side effects you can help provide more information on the safety of our medicines.

Product Quality Complaints should also be reported to ITF Pharma Ltd Medical Information on: **0800 098 4040** or **UK.Medical.Information@italfarmacogroup.com**

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Q&A

Duvyzat® (givinostat)

What side effects can Duvyzat® cause?

Duvyzat® may be associated with decreased blood platelet counts. The dose of Duvyzat® may be reduced in cases of persistent decrease in platelet count (thrombocytopenia) and your doctor may discontinue your treatment with givinostat if abnormalities persist.

Duvyzat® may be associated with increased levels of fats (such as triglycerides) in your blood. The dose of givinostat may be reduced in cases of persistent increase in levels of fats in your blood. Your doctor may discontinue treatment if abnormalities persist.

You may experience diarrhoea and vomiting while taking Duvyzat®. Your doctor may reduce the dose of Duvyzat® based on severity of diarrhoea or discontinue treatment if abnormalities persist.

Your doctor may check your heart function when starting Duvyzat® if you have an underlying heart problem or if you use medicines that can cause irregular heartbeat. High doses of Duvyzat® (5 times higher than the recommended dose) may cause an irregular heartbeat. Your doctor will evaluate the use of Duvyzat® when there is an increased risk for abnormal heartbeat, narrow coronary arteries, abnormal mineral levels in body or concomitant use of other medicines.

Contact your doctor, who may stop your therapy with Duvyzat®, if any of the above conditions appear.

What medicines should be avoided with Duvyzat®?

Tell your doctor if you are taking, have recently taken, or might take any other medicines. In particular tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- medicines used to minimise the sensation of pain (anaesthetics, e.g. sevoflurane, propofol)
- medicines used to treat irregular heartbeat (e.g. amiodarone, sotalol)
- medicines used to treat nausea and vomiting (ondansetron)
- medicines used to treat some bacterial infections (fluconazole, azithromycin clarithromycin, ciprofloxacin)
- medicines used to treat severe mental health problems (aripiprazole, risperidone)
- medicines used to treat allergies (e.g. famotidine)

Q&A

Duvyzat® (givinostat)

How should Duvyzat® be taken?

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Duvyzat® is for oral use. The oral suspension must be shaken by hand for at least 30 seconds by continuously turning the bottle up and down until the oral suspension is mixed well and looks the same throughout. The suspension is dosed by the graduated oral syringe.

Ask your doctor, pharmacist or nurse to show you how to measure your prescribed dose.

- Take Duvyzat® as prescribed by your doctor (see Tables 1, 2, 3)
- The recommended dose of Duvyzat® is taken by mouth 2 times per day
- Take Duvyzat® with food to avoid the bitter taste of Duvyzat®
- Always take Duvyzat® using the oral syringe (5 mL) provided with Duvyzat®

The recommended dose of Duvyzat® depends on your body weight, as shown in **Table 1.**

Table 1: Recommended Duvyzat® dosage

Weight (kg)	Duvyzat® oral suspension volume to be taken twice daily
≥10 and <20	2.5mL
≥20 and <40	3.5mL
≥40 and <60	5.0mL
>60	6.0mL

If your prescribed dose is more than 5 mL, you will need to use the same oral syringe more than one time.

A dose reduction **(see Table 2 – next page)** may be applied by your doctor if the following situations appear:

- decreased platelet count
- moderate or severe diarrhoea (more than 4 stools per day)
- increased levels of fats in your blood

What if I need a dose reduction?

Table 2: First dose reduction

Weight (kg)	Duvyzat® oral suspension volume to be taken twice daily
≥10 and <20	2.0mL
≥20 and <40	2.5mL
≥40 and <60	3.5mL
>60	4.5mL

If the above abnormalities persist, your doctor may further reduce your dose **(see Table 3 below).**

Table 3: Second dose reduction

Weight (kg)	Duvyzat® oral suspension volume to be taken twice daily
≥10 and <20	1.5mL
≥20 and <40	2.0mL
≥40 and <60	3.0mL
>60	4.0mL

If these abnormalities still persist or in case of irregular heartbeat, your doctor may consider discontinuation of Duvyzat®.

Q&A

Duvyzat® (givinostat)

What if a dose of Duvyzat® is forgotten or missed?

If you forget a dose, take the next dose when needed. Do not take a double dose. It is important to take the correct dose. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

How should Duvyzat® be stored?

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Once opened, use within 60 days. Discard any unused Duvyzat® oral suspension remaining after 60 days of first opening of the container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

What did the Phase 3 clinical trials for Duvyzat® show?

Duvyzat®'s first completed Phase 3 trial was called EPIDYS, a multicentre, randomised, double-blind, placebo-controlled trial that evaluated the efficacy and safety of givinostat in treating Duchenne muscular dystrophy (NCT02851797).

In the EPIDYS study, a total of 179 ambulant boys six years of age or older received either Duvyzat® twice daily or placebo, in addition to glucocorticosteroid treatment. The EPIDYS study met its primary endpoint demonstrating that patients on givinostat showed a statistically significant and clinically meaningful difference in time to complete the four-stair climb assessment compared to placebo.

Duvyzat® also showed favourable results on key secondary endpoints (not statistically significant) including North Star Ambulatory Assessment (NSAA), and fat infiltration evaluation by magnetic resonance imaging. Most adverse effects observed with givinostat were mild to moderate in severity.

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