

Dosing & monitoring for Duvyzat[®] (givinostat)

Your doctor has prescribed you a medication called Duvyzat[®], which contains the active substance givinostat. Duvyzat[®] is used to treat Duchenne muscular dystrophy (DMD) resulting from a genetic defect that affects normal muscle function. This results in an abnormality in a muscle protein called dystrophin which is needed for muscles to work properly. This abnormality leads to muscle degradation. Duvyzat[®] slows muscle degradation.

How to take Duvyzat[®]

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. The recommended dose of Duvyzat[®] depends on your body weight.

Your body weight:

Blank space for your doctor to write in body weight

Your Duvyzat[®] recommended dose:

Your Duvyzat[®] modification dose 1:

Your Duvyzat[®] modification dose 2:

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

Method of administration

- ◆ Duvyzat[®] is for oral use
- ◆ The recommended dose of Duvyzat[®] is taken by mouth 2 times per day and with food to avoid the bitter taste of the medicine
- ◆ Duvyzat[®] 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
- ◆ Duvyzat[®] is dosed by the graduated oral syringe. Always use the oral syringe (5 mL) provided in the medicine box
- ◆ Please read the patient leaflet provided in the medicine box for further information.

If you take more Duvyzat[®] than you should.

Contact your doctor or a hospital if you take more than the prescribed dose of Duvyzat[®].



If you forget a dose, take the next dose when planned.

Do not take a double dose.



Do not stop taking Duvyzat[®] without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.



Please bring this card to all your appointments so the results can be added, and future appointment dates can be checked and confirmed.

Monitoring whilst on Duvyzat®



It is important that you are monitored whilst on Duvyzat®. The table below has been completed by your doctor and highlights the dates that you must have the following tests completed.

	Platelets		Triglycerides		Body weight	
At the start of treatment	Date:		Date:		Date:	
	Result:		Result:		Result:	
Month 1: Week 2	Date:		Date:		Date:	
	Result:		Result:		Result:	
Month 1: Week 4	Date:		Month 1 triglycerides test can take place any time during month 1		Date:	
	Result:				Result:	
Month 2: Week 6	Date:				Date:	
	Result:				Result:	
Month 2: Week 8	Date:				Date:	
	Result:				Result:	
Month 3	Date:		Date:		Date:	
	Result:		Result:		Result:	
Month 6	Date:		Date:		Date:	
	Result:		Result:		Result:	
Ongoing	Every 3 months		Every 6 months		As required	

It is important to monitor your platelets and triglycerides to help prevent complications

Duvyzat® can cause dose-related thrombocytopenia and other signs of myelosuppression, including decreased hemoglobin and neutropenia. Duvyzat® can also cause elevations in triglycerides.

Gastrointestinal disturbances

Always talk to your healthcare professional if you experience diarrhoea, nausea/vomiting, or abdominal pain.

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. 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.

Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any 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>

By reporting side effects, you can help provide more information on the safety of this medicine. This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See <https://yellowcard.mhra.gov.uk> for how to report side effects.