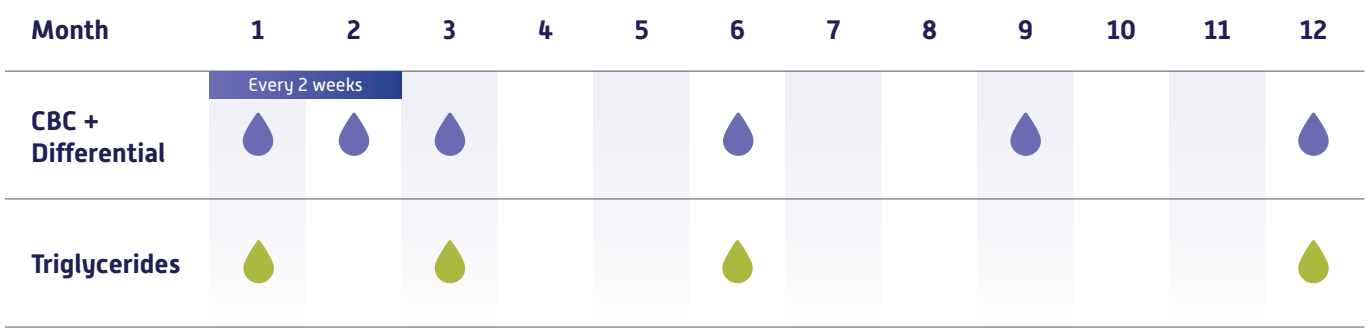
Ongoing monitoring with DUVYZAT

After performing baseline testing and prescribing DUVYZAT, ongoing monitoring with just 2 simple blood tests helps to keep your patients on track.

Duvyzat™ (givinostat)

Ongoing monitoring doesn't need to be done in your office. Ensure your patients stay the course with regular monitoring for the first year by directing them to a nearby lab.

Monitoring in the first year of treatment with DUVYZAT



CBC + Differential

Monitor blood counts every 2 weeks for the first 2 months of treatment, at month 3, and then every 3 months thereafter

Triglycerides

Monitor triglycerides at 1 month, 3 months, 6 months, and then every 6 months thereafter

Depending on the results of these tests, it may be necessary to modify the dosage of DUVYZAT. Additional guidance for dose modification can be found on DUVYZATHCP.com.

After the first 3 months of treatment with DUVYZAT, your patient's blood monitoring will become less frequent.

CBC, complete blood count.

Indication

DUVYZAT is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

Important Safety Information

Warnings and precautions

- Hematological Changes: DUVYZAT can cause dose-related thrombocytopenia and other signs of myelosuppression, including anemia and neutropenia. Monitor platelets; dosage adjustment or discontinuation may be needed.

Please see additional Important Safety Information on reverse.
Please see full Prescribing Information and Medication Guide in pocket.

Help your patients stay on track

Additional guidance for ongoing monitoring

- Closely monitor patients when DUVYZAT is used in combination with an oral CYP3A4 sensitive substrate or a sensitive substrate of the OCT2 transporter, for which a small change in substrate plasma concentration may lead to serious toxicities
- Avoid concomitant use with other drugs that prolong the QTc interval
  - Monitor ECG if concomitant use cannot be avoided

FOR MORE INFORMATION ON DOSING AND MONITORING, PLEASE SCAN THE QR CODE.

ECG, electrocardiogram; OCT2, organic cation transporter 2; QTc, corrected QT interval.

Important Safety Information (cont'd)

Warnings and precautions (cont'd)

- Increased Triglycerides: An increase in triglycerides can occur; dosage modification may be needed. Discontinuation may be needed.
- Gastrointestinal Disturbances: Adjust dosage if moderate or severe diarrhea occurs. Antiemetics or antidiarrheal medications may be considered during treatment with DUVYZAT. Discontinue DUVYZAT if the symptoms persist.
- QTc Prolongation: Avoid use of DUVYZAT in patients who are at an increased risk for ventricular arrhythmias.

Recommended Evaluation and Testing Before Initiation of DUVYZAT:

Obtain and evaluate baseline platelet counts and triglycerides prior to initiation of DUVYZAT. Do not initiate DUVYZAT in patients with a platelet count less than 150 x 10^9/L. Monitor platelet counts and triglycerides as recommended during treatment to determine if dosage modifications are needed.

In addition, in patients with underlying cardiac disease or taking concomitant medications that cause QT prolongation, obtain ECGs when initiating treatment with DUVYZAT, during concomitant use, and as clinically indicated.

Most Common Adverse Reactions:

Most common adverse reactions (≥10% in DUVYZAT-treated patients) are diarrhea, abdominal pain, thrombocytopenia, nausea/vomiting, hypertriglyceridemia, and pyrexia.

To report SUSPECTED ADVERSE REACTIONS, contact ITF Therapeutics LLC at 1-833-582-4312 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information on reverse.
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Reference: DUVYZAT. Prescribing information. ITF Therapeutics; 2024.

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