DUVYZAT™ (givinostat) FAQ

September 2025

- **What is DUVYZAT™?**
  - DUVYZAT™ (givinostat) is an 'HDAC inhibitor', which helps reduce inflammation, increase muscle repair and slow the loss of muscle. DUVYZAT is **not** a steroid.

- **How does it work?**
  - DUVYZAT works by blocking enzymes called histone deacetylases (HDACs), which are involved in turning genes 'on' and 'off' within cells and can reduce muscle regeneration in Duchenne. By inhibiting HDAC activity, DUVYZAT may help to activate muscle repair mechanisms to increase muscle fiber regeneration, reduce inflammation, and reduce fibrosis.

- **How is DUVYZAT administered?**
  - DUVYZAT is administered as an oral suspension (liquid) given by mouth two times a day (once in the morning and once at night) with food.
  - The recommended dosage of DUVYZAT™ is determined by the individual's body weight

- **Who is eligible for Duvyzat?**
  - DUVYZAT is approved for people with Duchenne who are six years of age and older.
  - DUVYZAT is not specific to any genetic variants. It does not have any contraindications related to specific genetic variants (meaning people with all genetic variants should be eligible).

- **Important things to know about DUVYZAT**
  - It is important to monitor platelet levels before and while taking DUVYZAT. An increase in triglycerides (a type of fat in the body) can also occur. Your doctor may order labs and adjust the dose or discontinue the medication if needed
  - Talk to your doctor if you have any heart problems or if you take any medicines that could increase your chance for irregular heart rhythms as DUVYZAT may cause QTc prolongation
  - Dosage modifications may also be needed for moderate or severe diarrhea
  - You can find the full prescribing label for Duvyzat here

- **What are the possible side effects of DUVYZAT?**
  - The most common side effects include diarrhea, abdominal pain, a decrease in platelets (which can lead to increased bleeding), nausea/vomiting, an increase in triglycerides (a type of fat in the body) and fever.
  - If you/your child notices any side effects, contact your neuromuscular provider

- **What precautions are needed while taking DUVYZAT?**
  - People with platelet counts less than 150 x 109/L should not take DUVYZAT™. It's important to talk with your neuromuscular provider about risks, benefits, and precautions before starting any medications.
  - Platelet counts and triglycerides should be monitored as recommended during treatment to determine if changes in dosage are needed

    - In patients with underlying cardiac disease or taking other medications that cause QT prolongation, it is important to obtain ECGs before initiating treatment with DUVYZAT, during use, and as clinically indicated

- **How does my child get access to DUVYZAT?**
    - If you want to know if your child is eligible to receive DUVYZAT, call your neuromuscular team to discuss whether DUVYZAT is right for your child.
    - If you and your neuromuscular team decide that DUVYZAT is right for your child, your neuromuscular provider will submit an enrollment form to ITF ARC
    - Your neuromuscular team and ITF ARC will work together to obtain insurance approval
    - If approved by your insurance, a specialty pharmacy will ship the medication to your home.
    - Learn more about access & coverage resources for DUVYZAT here

- **Learn more about clinical trials of DUVYZAT™**

- **Video Library**
    - Webinar: Community Update with ITF Therapeutics - Introducing DUVYZAT
    - Webinar: Overview of DUVYZAT and Access Resources