FAQs about DUVYZAT

Duvyzat™ (givinostat)

Our team at ITF Therapeutics LLC is very pleased to share with you the exciting news that the United States Food and Drug Administration (FDA) has approved DUVYZAT™ (givinostat) for the treatment of patients 6 years of age and older with Duchenne muscular dystrophy (DMD). We understand that you may have many questions at this time and have prepared the below list of FAQs to provide more details about DUVYZAT. For additional information, please visit DUVYZAT.com or speak with your doctor.

1. What is DUVYZAT and what is its regulatory approval status in the US?

DUVYZAT is a prescription medicine for DMD in patients who are 6 years of age and older. It is a histone deacetylase (HDAC) inhibitor. It was approved by the US FDA on March 21, 2024. You can find more information about what DUVYZAT is and how it works in the patient Medication Guide on DUVYZAT.com.

2. Who is eligible for treatment with DUVYZAT?

DUVYZAT is for patients in the US with DMD who are 6 years of age and older. DMD is a genetic disease, which means that it's caused by changes, or mutations, in genes. DMD may be caused by different types of genetic mutations. Doctors may prescribe DUVYZAT regardless of mutation.

For more information about eligibility for treatment with DUVYZAT, please speak with your doctor.

3. Is it possible for patients to access DUVYZAT now?

Our team has been working to make DUVYZAT available as quickly as possible. We are planning for it to be available to patients in the third quarter of 2024. In the meantime, we are working to make sure that programs and logistical support will be ready to serve patients with DMD, their families, and doctors.

We will share updates on DUVYZAT availability in the US on DUVYZAT.com.

4. Will patients receiving DUVYZAT as part of a clinical trial be able to continue to access treatment?

We are committed to working with clinical trial patients to make sure they can keep taking DUVYZAT. We will work with clinical trial sites to help patients transition to the commercially available product. Clinical trial patients and caregivers who would like more information should speak with representatives from their site of care.

5. How much will DUVYZAT cost?

The commercial cost of DUVYZAT has not been determined yet. However, our team is committed to making DUVYZAT available to appropriate patients with DMD in the US as quickly as possible. We will share updates on DUVYZAT in the US on DUVYZAT.com.

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6. Will there be a patient assistance program in place to support access to DUVYZAT?

We will offer a range of services to support access to DUVYZAT. We are in the process of gathering feedback from the DMD community to make sure the programs and services we develop meet the needs of patients and their families.

We will share more information about these programs and services on DUVYZAT.com. We will also share updates directly with patient advocacy groups serving the DMD community.

7. Will DUVYZAT be available for patients with Becker muscular dystrophy?

We recognize the significant unmet medical needs of people living with Becker muscular dystrophy (BMD) and their families. Clinical development for BMD is in early stages. Your physician is the best resource for you at this time.

8. Who is ITF Therapeutics?

ITF Therapeutics is the US-based rare disease division of Italfarmaco S.p.A. Founded in 1938 in Milan, Italy, Italfarmaco is a private global pharmaceutical company that has led the successful development of many innovative therapeutic products approved for use by patients around the world. The company operates in more than 60 countries on 5 continents and continues to advance promising research to address unmet medical needs in a wide range of therapeutic areas.

In January 2024, Italfarmaco launched ITF Therapeutics as a new division in the United States with a focus on the development and commercialization of products to treat rare diseases, including DMD. Building on a legacy grounded in collaboration and innovation, ITF Therapeutics strives to partner with leaders from the US patient advocacy and treatment communities to ensure that our programs reflect and support their unique needs and goals. The establishment of ITF Therapeutics also reflects Italfarmaco's goal to build a world-class team of experts who share a passion to make a positive impact for rare disease communities. For more information about ITF Therapeutics, please visit itftherapeutics.com.

Indication and Important Safety Information

What is DUVYZAT?

DUVYZAT is a prescription medicine that is used 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 6 years of age.

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, and a decrease in their numbers can lead to an increased risk of bleeding or bruising. Your healthcare provider will check your blood count before you start DUVYZAT and regularly during treatment for any signs of

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thrombocytopenia. Call your healthcare provider right away if you notice any unusual bleeding or small red or purple spots on the skin called petechiae. Your healthcare provider may change your dose of DUVYZAT if your blood platelet counts continue to be low or may stop your treatment with DUVYZAT.

- **Increased levels of fat (triglycerides) in your blood.** You may not have any symptoms, so your healthcare provider will do blood tests before you start DUVYZAT and regularly during treatment to check your triglyceride levels. Your healthcare provider may change your dose of DUVYZAT if your triglyceride levels continue to be high or may stop your treatment with DUVYZAT.
- **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 healthcare provider. Your healthcare provider may change your dose of DUVYZAT if the diarrhea cannot be managed or does not go away. Your healthcare provider may also stop your treatment with DUVYZAT.

Before taking DUVYZAT, tell your healthcare provider about all of your medical conditions, including if you:

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

Tell your healthcare provider 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 healthcare provider.

DUVYZAT can cause serious side effects, including:

- **See "What is the most important information I should know about DUVYZAT?"**
- **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 healthcare provider right away if you feel faint, have an irregular heartbeat, feel dizzy, or lose consciousness.

The most common side effects of DUVYZAT included diarrhea, nausea, vomiting, stomach pain, low platelet counts in the blood, increased fat level in the blood and fever.

These are not all of the possible side effects of DUVYZAT. For more information, ask your healthcare provider or pharmacist.

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

Please see full Prescribing Information and Medication Guide.

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