

Duvyzat® ▼ (givinostat)

This medicine is subject to additional monitoring

A guide to your treatment

For adults and children age 16+

Information about reporting side effects can be found on the back page.
If you have any questions about dosing or administering Duvyzat®, please speak with your healthcare team.



What is Duvyzat®?



Duvyzat® (givinostat) is a medication used to treat Duchenne muscular dystrophy

Duvyzat® (givinostat) is a medicine designed to target one of the underlying biological changes seen in Duchenne muscular dystrophy (DMD). In DMD, the absence of dystrophin leads to repeated muscle damage. This triggers excessive inflammation and disrupts the normal repair cycle. A key part of this disruption is the overactivity of enzymes called HDACs, which prevent muscle cells from switching on the genes needed for repair.

Duvyzat® works by inhibiting these HDAC enzymes. This helps reduce inflammation, limits the build-up of scar and fat tissue, and supports the muscle's natural ability to regenerate. It can be taken alongside standard treatments such as corticosteroids and may help to delay disease progression.

Duvyzat® is a medicine that doctors prescribe to treat Duchenne in people who are 6 years or older.

MyEveryDay Treatment



What does Duvyzat® look like?

Duvyzat® is an oral suspension and is taken twice daily with food. The colour of the liquid is faintly pink, and has been designed to taste like peach. It's in a bottle with a label and comes with a graduated oral syringe to help measure the right amount.

How does Duvyzat® work?



Duvyzat® limits HDAC protein activity, helping to support muscle regeneration

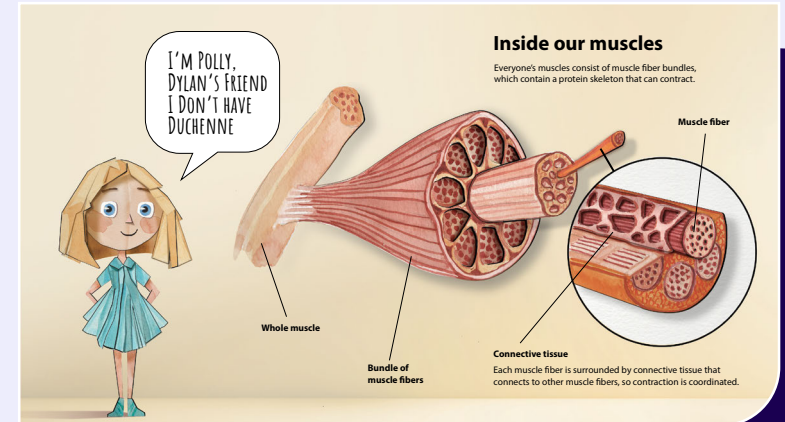
Duchenne muscular dystrophy is a genetic condition caused by changes in the dystrophin gene, which normally provides the instructions for making the dystrophin protein. When this gene is altered, the body is unable to produce functional dystrophin, and muscle cells become fragile and easily damaged during everyday activity.

This ongoing muscle damage triggers a cascade of biological responses. One consequence is that a group of enzymes called histone deacetylases (HDACs) become overly active. Excess HDAC activity disrupts the normal regulation of genes involved in muscle repair, contributes to chronic inflammation, and promotes the replacement of healthy muscle fibres with fibrotic and fatty tissue.

Duvyzat® contains the active ingredient givinostat, an HDAC inhibitor. By reducing HDAC activity, givinostat helps decrease inflammation and supports the regeneration of muscle tissue, which can help preserve muscle function and slow disease progression.

A glossary of words often used when explaining Duvyzat® can also be found on pages 9, 10, 24 and 25 of this book.

If you'd like to learn more about how Duvyzat® (givinostat) works, we've created a downloadable book with illustrations (examples shown below) to help explain.



The full story can be viewed on the website at: www.myeveryday.support/home (desktop only) and can also be downloaded as a PDF (desktop, tablet and mobile).

Understanding the scientific terms



Here are some words and definitions often used to explain how Duvyzat[®] works

Most relevant scientific terms are listed, but if a term is unclear or missing, you can always ask your healthcare team too.

ACETYL GROUPS

Tiny chemical tags that change how proteins behave.

ACETYLATION

Adding acetyl groups to a protein to change activity.

CONNECTIVE TISSUE

Strong material in the body that holds muscles and organs together.

DEACETYLATION

Removing an acetyl group which can, depending on the target increase or decrease protein activity.

DNA

Instruction manual found in most cells, telling them how to work.

FAP CELLS

Fibro-adipogenic progenitors or 'FAP' cells help repair muscle but can form scar or fat.

FAT CELLS

Cells that store fat, and replaces muscle lost in Duchenne.

FIBROBLASTS

Cells that make connective tissue and help healing.

GROWTH FACTORS

Signals that tell cells to grow, repair, or divide.

HAT ENZYMES

Proteins that add acetyl groups to other proteins.

HDAC (HISTONE DEACETYLASE) PROTEIN

A protein that removes acetyl groups from histones. In Duchenne HDAC is overactive, promoting inflammation and hindering muscle regeneration.

HISTONES

Proteins that DNA wraps around to stay organised.

IMMUNE CELLS

Cells that protect the body from germs and damage.

INFLAMMATION

The body's natural, protective response to injury, germs, or irritation. Often resulting in swelling and redness.

MUSCLE FIBRES

Long cells that make up your muscles, they contract and relax helping you move.

PROTEIN SKELETON

Inner support structure that keeps a cell's shape.

STEM CELLS

Cells that divide into specialised cells (such as muscle cells) or make more stem cells.

These medical definitions have been worded for the intended audience and accurately reflect the current scientific information available.

MyEveryDay Learning



Getting started on Duvyzat®

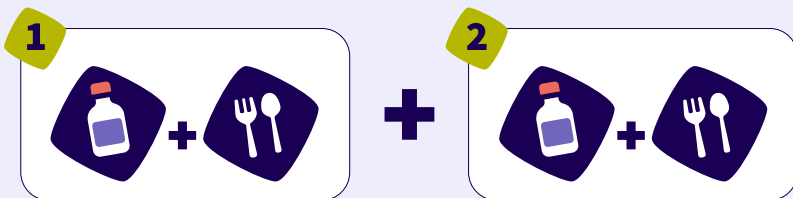


Information about how you should prepare to take the medicine

Duvyzat® needs to be taken twice daily, so it must become part of your daily routine.

The medication must always be taken exactly as prescribed by your doctor. If you have any doubts, ask your healthcare team.

Duvyzat® should be taken twice daily with food and it's best to take it with a meal. This might also make it easier not to forget it and a tasty meal can help mask the taste of Duvyzat® if required.



Try and take your medicine at the same time every day.

With practice, taking the medication will soon become routine.

An administration video is available on the website at:
www.myeveryday.support/starting-treatment

This video features a real patient. It is shown for illustrative purposes only, and individual experiences may vary.



The oral liquid is dosed and administered using a graduated syringe provided with the medication. The syringe should be rinsed with water after use – ready to reuse for each dose.

The precise dose of the medication is based on body weight and will be determined by your doctor. Be aware that the dosage may change during the course of treatment.

Please read the instructions on pages 14 and 15, and never adjust the dose of Duvyzat® yourself!

Important facts about dosing



Key considerations for Duvyzat® dosing and storage

Important

- Use Duvyzat® exactly as supplied in the bottle.
- Always use the syringe provided. Contact your healthcare team or pharmacist if you lose the syringe or throw it away by accident.
- If you forget a dose, simply continue with the next scheduled one. Do not take double to make up for a missed dose.
- If you take too much Duvyzat® by accident, contact your healthcare team or a hospital immediately.

Storage

- Do not use the medication after the expiry date stated on the packaging.
- After being opened Duvyzat® is stable for 60 days and must be discarded afterwards. It's a good idea to write the date you opened the bottle either on it or on the outer carton.
- This medicinal product does not require any special temperature storage conditions.

MyEveryDay
Dosing



How do we prepare the medicine?



Administration instructions for preparing and taking Duvyzat®

1 Mix well

Invert the bottle upside-down and back again for at least 30 seconds – until the liquid looks evenly mixed.

Not shaking the bottle enough may result in too much or too little of the active ingredient being administered.

2 Opening the bottle

Press down on the cap and turn it anticlockwise (to the left).

3 Preparing the medication

- Insert the syringe firmly into the bottle adapter.
- Turn the bottle upside down.
- Slowly pull the syringe plunger down to draw a small amount of liquid; then push the plunger all the way back up to remove any air bubbles.

- Draw the plunger down to the mark on the syringe that matches the prescribed dose in ml.
- Keep the plunger in this position and turn the bottle upright again.
- Carefully pull the syringe out of the adapter. Take the medication right away; do not store it in the syringe.

4 Administering the medication

- Gently insert the syringe into the mouth and place the tip against the inside of the cheek.
- Slowly press the plunger all the way down until the syringe is empty.

5 Well done! Just a few final steps

- Close the bottle again.
- Rinse the syringe with water so you can use it again and allow it to dry thoroughly.
- Store the syringe in a clean, dry place.

Important note

If the prescribed dose is more than 5 ml, repeat steps 3 and 4 until the full dose has been given.



What are the known side effects?



Unfortunately, there's no way to predict whether side effects will occur

You should watch out for potential signs, and inform your healthcare team if any issues arise.

Known side-effects:



Reduced platelet count (thrombocytopenia)

If you have unusual bleeding or small red to purple spots on the skin, inform your healthcare team immediately.



Increased blood fat levels (elevated triglycerides)

These changes in the blood initially show no symptoms but are detected early thanks to regular monitoring.



Diarrhoea

If you experience diarrhoea, keep track of how often it occurs and how severe it is, and contact your healthcare team. It is important to stay well hydrated.



Changes in heart rhythm (QTc prolongation)

Some people may experience changes in the heart's rhythm. This usually causes no symptoms, but your healthcare team may monitor this with heart tests called ECGs.

**MyEveryDay
Wellbeing**



Important Note



Serious side effects can also occur during treatment with Duvyzat®. On this basis, your healthcare team will carry out regular tests and take appropriate action if any abnormalities are detected.

Are there any other side effects?



Additional side effects may occur – some are very common and some common

Very common (may affect more than 1 in 10 people)

- abdominal pain
- decrease in blood platelet count (thrombocytopenia)
- diarrhoea
- elevated levels of blood fats (triglycerides)
- fever
- nausea
- vomiting

Common (may affect up to 1 in 10 people)

- constipation
- decreased appetite
- fatigue
- joint pain (arthralgia)
- muscle pain (myalgia)
- rash

Not known: frequency cannot be estimated from the available data: hypothyroidism and/or increased in thyroid stimulating hormone



Reporting side effects



Instructions are on the back page of this booklet, and you can always refer to the instructions in the Duvyzat® Patient Information Leaflet (PIL) regarding how to report side effects.

What about safety check-ups?



Regular testing (or monitoring) is very important with Duvyzat®

Before starting treatment, your healthcare team will carefully assess whether the treatment is suitable and if there is anything special to watch out for.

After starting treatment, your healthcare team will closely monitor your child's health through regular blood tests and may also monitor your heart beat with regular ECGs. This way, any possible side effects can be detected early, and the right measures can be taken.

These blood values are checked regularly:



Blood cell count

To check the levels of different types of cells in your blood



Triglycerides

To check the levels of a type of fat in your blood

Changes in heart rhythm

Duvyzat® can affect the way your heart beats (QTc prolongation) and caution is advised when taking Duvyzat® with other products known to also change heart rhythm. For example, certain sleep medicines, medicines used during operations, heart medicines, sickness medicines, some antibiotics, mental health medicines, and some allergy medicines. This list is not exhaustive and your healthcare team will monitor you if there is any concern.

Interactions with other medications

Certain medications can increase the risk of side effects from Duvyzat®. Likewise, Duvyzat® can strengthen or weaken the effects of other medicines. It's important to inform your healthcare team about all other medications your child is taking, including supplements and herbal remedies.

Intolerances

Duvyzat® contains sorbitol. Sorbitol is a source of fructose. If your child has an intolerance to certain sugars, such as fructose, discuss this with your doctor. Duvyzat® must not be used in cases of hypersensitivity to the active substance or any of the other ingredients. A list of other ingredients can be found in the package insert for Duvyzat®.

Keep a list

Make a list of all your medications and supplements – you can even use the page 27 at the end of this brochure.



What about ongoing monitoring?



Stay on track with monitoring

Close monitoring will continue throughout treatment

During regular follow-up appointments your blood values will continue to be checked, in addition to any other tests your health team recommend.

For some tests, it may be necessary to fast – check before the appointment whether it's okay to eat beforehand.

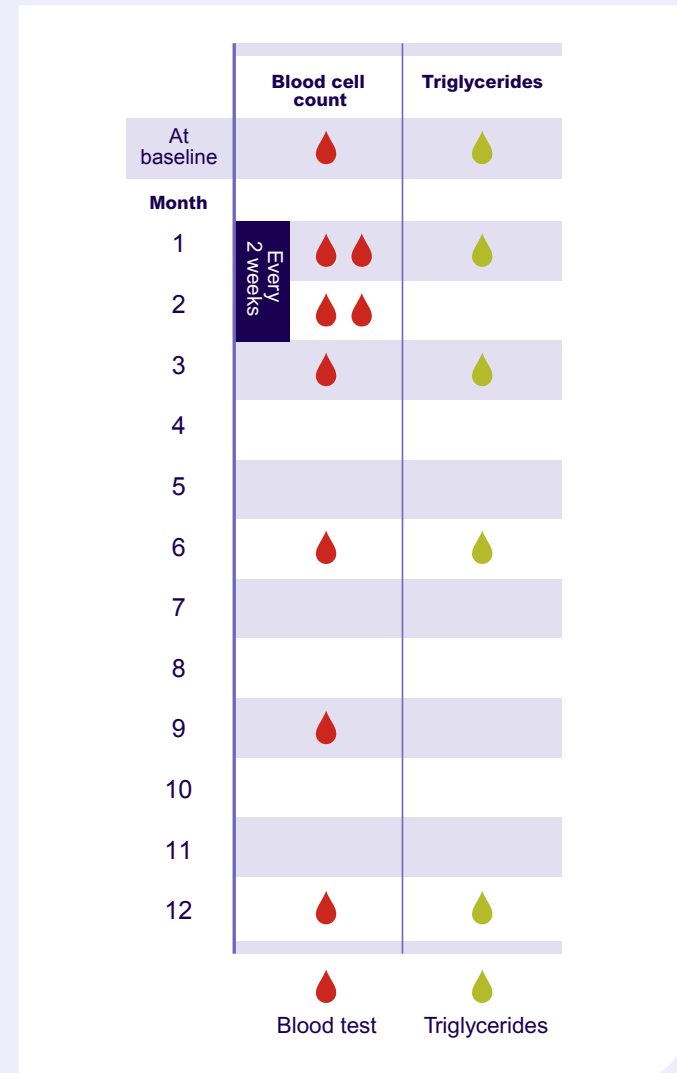
In the first 2 months of treatment, blood tests usually take place every 2 weeks. In some cases, your healthcare team may recommend more frequent checks – this is no cause for concern.

Got more questions?



Please see full Duvyzat® Patient Information Leaflet (PIL) and talk to your healthcare team.

Blood monitoring: This overview helps you to keep track of all blood tests during the first year of treatment.



ECG monitoring: Your healthcare team may recommend additional ECG monitoring due to underlying cardiac disease or other medications you are taking.

What if some words are unfamiliar?



Here are definitions of important medical words about your Duvyzat® treatment

Important medical words used in this booklet are listed, but if a term is unclear or missing, you can always ask your healthcare team too.

DUCHENNE MUSCULAR DYSTROPHY (DMD)

A rare muscle disease where the muscles gradually weaken over time. It almost only affects boys and usually begins in early childhood.

DYSTROPHIN

This is a protein that ensures the stability of muscle cells. In Duchenne, it's missing or doesn't work properly.

GIVINOSTAT

This is the active ingredient in Duvyzat®, which can help reduce inflammation in the muscles and slow down muscle breakdown.

HDAC (HISTONE DEACETYLASE)

A protein that removes acetyl groups from histones. In Duchenne HDAC is overactive, promoting inflammation and hindering muscle regeneration.

SORBITOL

A sugar substitute frequently used in food and medicine products.

THROMBOCYTES (PLATELETS)

Small pieces of cells that help wounds stop bleeding. If there are too few of them in the blood, bleeding and bruising will occur more easily.

THROMBOCYTOPENIA

This is where there is a reduced number of platelets in the blood. It can lead to increased tendency to bleed or small red spots on the skin.

TRIGLYCERIDES (BLOOD FATS)

These are a type of fat that are found within blood. If there are too many of them in the blood, this is referred to as "elevated blood fat levels". This is usually not noticeable, but it can be detected in the laboratory.

CORTISONE

Medications that can inhibit inflammation in the body.

ORAL SUSPENSION

A liquid that has a medicine mixed into it, that is then swallowed. Duvyzat® is this kind of suspension – it is administered using a special syringe.

CHROMOSOME

A chromosome is a structure inside your cells that carries your DNA.

X CHROMOSOME

It is a sex-determination chromosome. Females have two copies [XX], and males have one X and one Y [XY]. The genetic defect in Duchenne is located on the X chromosome, which is why almost only boys are affected.

These medical definitions have been worded for the intended audience and accurately reflect the current scientific information available.



ITF PHARMA UK
ITALFARMACO® GROUP

This resource has been created and funded by ITF Pharma Ltd.

It is intended to provide helpful information and should not replace advice from your healthcare team.

Job code: GB-DVZ-26-00008 V2
Date of preparation: June 2026



Reporting 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.