

MODEYSO is the **first and only** treatment for adults and children 1 year of age and older with a certain type of brain tumor called diffuse midline glioma that has a specific "H3 K27M" gene mutation and has gotten worse after other treatments



HEAD TO HOPE

FDA, US Food and Drug Administration.

WHAT IS MODEYSO?

MODEYSO is a prescription medicine used to treat adults and children 1 year of age and older with a certain type of brain tumor called diffuse midline glioma that has a specific "H3 K27M" gene mutation **and** has gotten worse after other treatments.

It is not known if MODEYSO is safe and effective in children less than 1 year of age.

SELECT IMPORTANT SAFETY INFORMATION

What is the most important information I should know about MODEYSO?

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

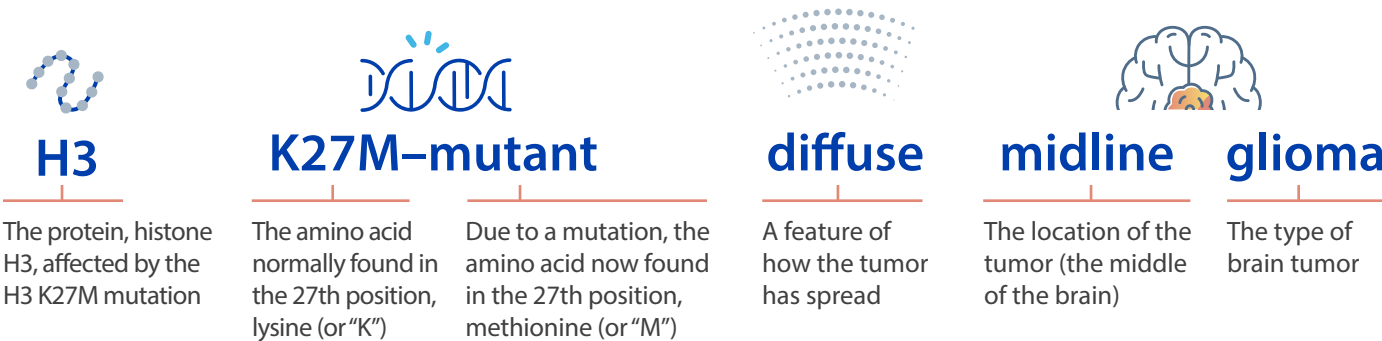
- have heart failure or heart rhythm problems, including QT prolongation or long QT syndrome. MODEYSO may increase the risk of heart rhythm problems.

Please see additional Important Safety Information throughout, full Prescribing Information at [MODEYSO.com](https://www.MODEYSO.com), and discuss with your doctor.


MODEYSO[™]
(dordaviprone) capsules
125 mg

What is MODEYSO?

MODEYSO is a prescription medicine used to treat adults and children 1 year of age and older with certain types of brain tumors called H3 K27M–mutant diffuse midline gliomas that have gotten worse after other treatments.



MODEYSO may alter the process behind H3 K27M–mutant diffuse midline glioma formation

In laboratory studies of H3 K27M–mutant diffuse midline glioma, MODEYSO has been shown to alter the growth and survival of tumor cells.

- MODEYSO may affect how tumor cells use energy and activate signals that lead to tumor cell death
- MODEYSO may reverse the loss of a chemical marker on histone H3 (trimethylation loss, also called H3 K27me3 loss), which is often disrupted by the H3 K27M mutation

How MODEYSO was studied

The efficacy of MODEYSO was studied in adult and pediatric patients with progressive and measurable H3 K27M–mutant diffuse midline glioma who were previously treated with at least radiation therapy.

Prespecified eligibility criteria were designed based on guidance provided by the FDA.

- The first 50 patients who met eligibility for the integrated efficacy analysis were enrolled in the study
- This trial evaluated how many people responded to treatment using special guidelines called RANO 2.0 criteria and how long their responses lasted

Your doctor may perform a test such as next-generation sequencing (NGS) or immunohistochemistry (IHC) to determine your H3 K27M mutational status and see if you may be eligible for MODEYSO.

RANO, Response Assessment in Neuro-Oncology.

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What is the most important information I should know about MODEYSO? (cont’d)

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

- are pregnant or plan to become pregnant. MODEYSO can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with MODEYSO.
 - Your healthcare provider should check to see if you are pregnant before you begin treatment with MODEYSO.

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What is the most important information I should know about MODEYSO? (cont’d)

- Females who are able to become pregnant should use effective birth control (contraception) during treatment with MODEYSO, and for 1 month after your last dose.
- Males with partners who are able to become pregnant should use effective contraception during treatment with MODEYSO, and for 1 month after your last dose.

Results with MODEYSO

Data are from the 50 patients with H3 K27M–mutant diffuse midline glioma who were included in the integrated efficacy analysis.

RESPONSE TO TREATMENT

22% Percentage of patients (11 out of 50) who responded to MODEYSO treatment based on RANO 2.0 criteria

PARTIAL RESPONSE

16% (8 people) had a partial response, which means the tumor shrank by 50% or more*

MINOR RESPONSE

6% (3 people) had a minor response, which means the tumor shrank by 25% to 50%†

Among the 11 people who responded to MODEYSO, the median‡ time to response was **3.6 months**.§

How long people responded to MODEYSO||

10.3 months was the median‡ length of time responses lasted in the 11 people who responded to MODEYSO.

*Applies to enhancing and non-enhancing tumors. In addition, there couldn't be any new or growing tumors, symptoms had to stay the same or improve, and the patient had to be on the same or a lower dose of steroids.
†Applies only to non-enhancing tumors. There couldn't be any new or growing tumors, symptoms had to stay the same or improve, and the patient had to be on the same or a lower dose of steroids.
‡Median is the middle number in a group of numbers when arranged from lowest to highest.
§Time to response is the length of time between starting a treatment and seeing a response.
||Duration of response is the length of time from when a tumor begins to respond to treatment until it stops responding or gets worse.

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What is the most important information I should know about MODEYSO? (cont'd)

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

- are breastfeeding or plan to breastfeed. It is not known if MODEYSO passes into breast milk. Do not breastfeed during treatment with MODEYSO and for 1 week after your last dose. Talk to your healthcare provider about the best way to feed your baby during this time.

What to do before taking MODEYSO

Before receiving MODEYSO, tell your doctor about all of your medical conditions, including if you:

- have heart failure or heart rhythm problems, including QT prolongation and long QT syndrome
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed



SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about all the medicines you take, including:

- prescription and over-the-counter medicines, vitamins, and herbal supplements.

MODEYSO and other medicines may affect the way each other work and may cause serious side effects. You can ask your healthcare provider or pharmacist for a list of medications that interact with MODEYSO.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist. **Do not** start or stop taking any new medicines without first talking to your healthcare provider.

Possible side effects of MODEYSO

What are the possible side effects of MODEYSO?

MODEYSO may cause serious side effects, including:

- **Allergic reactions.** Allergic reactions may happen during treatment with MODEYSO and can be severe. Stop taking MODEYSO and get immediate emergency medical help right away if you get any signs or symptoms of allergic reactions, including:
 - rash
 - feeling faint or dizzy
 - hives
 - wheezing or trouble breathing
 - fever
 - swelling of the face or throat
- **Heart rhythm problems (QTc interval prolongation).** MODEYSO can cause changes in the electrical activity of your heart and can increase your chance of getting a type of abnormal heart rhythm, called torsades de pointes, that can lead to sudden death. Before you start treatment and during treatment as needed, your healthcare provider will check your heart using an electrocardiograph (ECG) and check your blood levels of salts called electrolytes. Get emergency medical help right away if you get any signs or symptoms of abnormal heart rhythm, including:
 - feeling lightheaded or faint
 - heart palpitations
 - dizziness
 - shortness of breath
 - fast heartbeat

Possible side effects of MODEYSO (cont'd)

The most common side effects of MODEYSO include:



TIREDFNESS



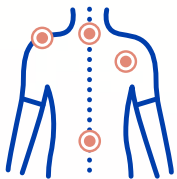
HEADACHE



VOMITING



NAUSEA



MUSCLE, JOINT,
AND BONE PAIN

The most common abnormal blood tests include decreased white blood cells, decreased red blood cells, decreased calcium, and increased liver enzymes.

MODEYSO may cause fertility problems in males and females, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of MODEYSO. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to Jazz Pharmaceuticals at 1-866-662-2679.

How to take MODEYSO

Take MODEYSO exactly as your doctor tells you. **Do not** change your dose or stop taking MODEYSO without talking to your doctor. Your doctor may change your dose of MODEYSO, temporarily stop, or completely stop your treatment with MODEYSO if you develop certain side effects.

MODEYSO 125-mg capsules should only be taken orally (by mouth). It is important to take the right number of MODEYSO capsules once a week, as instructed by your doctor:



Take MODEYSO capsules when your stomach is empty, either 1 hour before you eat or 3 hours after you've eaten



Take all the capsules needed for your dose at the same time, and do this once a week on the same day each week



Swallow the capsules whole with liquid; if you cannot swallow capsules whole, see the Instructions for Use for details on how to prepare and take the contents of the capsules in a suitable drink

If you are giving your child a dose of MODEYSO, the number of capsules in your child's prescribed dose depends on your child's weight, and their doctor will tell you how many to give.

MODEYSO should be stored at room temperature (68 °F to 77 °F, or 20 °C to 25 °C).

When to take MODEYSO

Guidance on when to add MODEYSO to your weekly routine, and what to do if you miss a dose

Sun	Mon	Tues	Wed	Thur	Fri	Sat
Take your dose of MODEYSO once per week and on the same day. This example uses Sunday, but you can choose the day of the week that fits your routine						
Take DOSE						
If DOSE is missed at any scheduled time	OR		If more than 2 days have passed, wait to take the next dose			
Take next DOSE						

If vomiting happens right after taking a dose of MODEYSO, **do not** take another dose. Instead, wait and take the next dose of MODEYSO on the next regularly scheduled day.

Stay under the care of your doctor during treatment with MODEYSO. If you take too much MODEYSO, call your doctor or go to the nearest hospital emergency room right away.

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 - feeling lightheaded or faint
 - heart palpitations
 - dizziness
 - shortness of breath
 - fast heartbeat

The most common side effects of MODEYSO include:

- tiredness
- nausea
- headache
- muscle, joint, and bone pain
- vomiting

The most common abnormal blood tests include decreased white blood cells, decreased red blood cells, decreased calcium, and increased liver enzymes.

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ChimerixCares™ is here to help you along the path of treatment with MODEYSO

Visit [ChimerixCares.com](https://www.ChimerixCares.com) to learn more

Please see full Prescribing Information, including both Patient Information and Instructions for Use, at [MODEYSO.com](https://www.MODEYSO.com), and discuss with your doctor.





MODEYSO is the first and only FDA-approved treatment for adults and children 1 year of age and older with H3 K27M–mutant diffuse midline gliomas that have gotten worse after other treatments.

- MODEYSO specifically targets the effects of the H3 K27M mutation that may have caused the diffuse midline glioma to develop
- The effectiveness of MODEYSO was evaluated in an integrated analysis of 50 patients with H3 K27M–mutant diffuse midline glioma
- MODEYSO is taken orally once a week and can be administered anywhere

To learn more, visit MODEYSO.com

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