

PATIENT INFORMATION
MODEYSO (moh-DAY-soh)
(dordaviprone)
capsules, for oral use

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 worsened after other treatments.

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

Before taking MODEYSO, tell your healthcare provider about all 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. 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.
 - **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.
- 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.

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.

How should I take MODEYSO?

- Take MODEYSO exactly as your healthcare provider tells you.
- Do not change your dose or stop taking MODEYSO without talking to your healthcare provider.
- Your healthcare provider may change your dose, temporarily stop, or completely stop treatment with MODEYSO if you develop certain side effects.
- Take MODEYSO 1 time each week on the same day of the week. Take all of the capsules prescribed for your dose at the same time.
- Take MODEYSO on an empty stomach, at least 1 hour before or 3 hours after eating food.
- Swallow MODEYSO capsules whole. If the capsules cannot be swallowed whole, see the detailed **Instructions for Use** for how to prepare and take or give MODEYSO as a liquid.
- If vomiting happens after taking a dose of MODEYSO, do not take another dose. Take the next dose of MODEYSO on the next regularly scheduled weekly day of the week.
- If you miss a weekly dose of MODEYSO by:
 - **2 days or less**, take the missed dose as soon as you remember. Take the next dose of MODEYSO on the next regularly scheduled day of the week.
 - **More than 2 days**, skip the missed dose and take the next dose of MODEYSO on the next regularly scheduled day of the week.

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 that can lead to sudden death called torsades de pointes. 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	

The most common side effects of MODEYSO include:

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

You may also report side effects to Chimerix, Inc. at 1-866-662-2679.

How should I store MODEYSO?

- Store MODEYSO at room temperature between 68°F to 77°F (20°C to 25°C).
- The MODEYSO bottle has a child-resistant closure.

Keep MODEYSO and all medicines out of the reach of children.

General information about the safe and effective use of MODEYSO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use MODEYSO for a condition for which it was not prescribed. Do not give MODEYSO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about MODEYSO that is written for health professionals.

What are the ingredients in MODEYSO?

Active ingredient: dordaviprone

Inactive ingredients: magnesium stearate, microcrystalline cellulose, and sodium starch glycolate. The capsule shell contains hypromellose and titanium dioxide. The black printing ink contains alcohol, D&C yellow #10, FD&C blue #1, FD&C blue #2, FD&C red #40, ferrousferic oxide, methyl alcohol, *N*-butyl alcohol, propylene glycol, and shellac glaze (20% esterified).

Distributed by:

Jazz Pharmaceuticals, Inc.
Palo Alto, CA 94306

For more information, contact Chimerix, Inc. at 1-866-662-2679.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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