

# Use Dispense As Written (DAW) to ensure your patients have access to EMFLAZA® and PTC Cares™.



Reid,  
Age 7

Mikey,  
Age 9

Actual EMFLAZA patients.

Dispense as Written (DAW) requirements help health care providers like you ensure patients get the right medication.

Use the following guide to find out which language or special instructions are required by your state or territory.

By utilizing DAW, your patients retain access to branded EMFLAZA® and the PTC Cares™ support services, including:

- Eligible patients receive financial and co-pay assistance via PTC Cares
- Adherence and Compliance support
- Less likelihood of interruptions in treatment.

Dispense quantity needed for ___ Days with ___ Refills	Dispense quantity needed for <b>15</b> Days with <b>5</b> Refills
Prescriber's Signature: Physician attests this is his/her signature. No Stamps.	Prescriber's Signature: Physician attests this is his/her signature. No Stamps.
<input checked="" type="checkbox"/> Dispense as Written Signature _____ Date _____	<input checked="" type="checkbox"/> Dispense as Written Signature _____ Date _____
<input checked="" type="checkbox"/> Substitution Permitted _____ Date _____	<input checked="" type="checkbox"/> Substitution Permitted _____ Date _____
<input checked="" type="checkbox"/> Supervising Physician Signature (where required) _____ Date _____	<input checked="" type="checkbox"/> Supervising Physician Signature (where required) _____ Date _____

## INDICATION & IMPORTANT SAFETY INFORMATION FOR EMFLAZA® (deflazacort)

**What is EMFLAZA® (deflazacort) used for?** EMFLAZA is a prescription medicine used to treat Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

Please see Indication and Important Safety Information on the back cover and accompanying full Prescribing Information.

  
**Emflaza®**  
 (deflazacort)  
 6 mg | 18 mg | 30 mg | 36 mg tablets  
 22.75 mg/mL oral suspension

## Specific Dispense as Written (DAW) Requirements by State or Territory

Refer to the chart below for state or territory-specific instructions on preserving your choice for branded medication. **Disclaimer: Note that information may change based on federal and local government updates; Please check your state or territory guidelines for the latest information.**

STATE	ON EACH PRESCRIPTION
<b>Alabama</b>	Sign on the appropriate prescription signature line.
<b>Alaska</b>	Handwrite "Brand Necessary" and sign.
<b>Arizona</b>	Expressly indicate that substitution is not allowed.
<b>Arkansas</b>	Handwrite "Brand Necessary" and sign.
<b>California</b>	Handwrite or verbally communicate "Do Not Substitute" or a similar expression. Allows use of preprinted "Do Not Substitute" as long as initialed.
<b>Colorado</b>	Handwrite "Dispense as Written" or initial a preprinted "Dispense as Written" box. Can be done electronically.
<b>Connecticut</b>	Indicate in own handwriting "DAW" or "Dispense as Written" along with the words "Medically Necessary."
<b>Delaware</b>	Indicate in own handwriting: "DAW," or "Dispense as Written."
<b>DOC</b>	Expressly indicate brand name in some manner.
<b>Florida</b>	Expressly indicate brand name in some manner.
<b>Georgia</b>	Handwrite "Brand Necessary" or "Brand Medically Necessary" and sign.
<b>Guam</b>	Handwrite "No Substitution" or abbreviate to "No Sub" on the face of the prescription.
<b>Hawaii</b>	Handwrite "Brand Necessary" or "Brand Medically Necessary" or product selection is allowed. Refer to Department of Health, Food, and Drug Branch.
<b>Idaho</b>	Expressly indicate brand name in some manner, and that substitution is not allowed.
<b>Illinois</b>	Mark the "May Not Substitute" box on the prescription.
<b>Indiana</b>	Sign on the appropriate line of the prescription.
<b>Iowa</b>	Expressly indicate substitution is not allowed.
<b>Kansas</b>	Sign on the appropriate line of the prescription and expressly indicate substitution not allowed.
<b>Kentucky</b>	Handwrite "Brand Medically Necessary" on the face of the prescription for Medicaid patients, or product selection is allowed. Indicate "Do Not Substitute" in some manner. Do not preprint on the prescription. Expressly indicate brand name in some manner.
<b>Louisiana</b>	Place a check mark in the "Dispense as Written" and/or "DAW" box.
<b>Maine</b>	Expressly indicate in some manner that substitution is not allowed. Check the preprinted box on the prescription.
<b>Maryland</b>	Handwrite "Brand Medically Necessary" on the face of the prescription for Medicaid patients. Product selection is allowed. Must indicate that substitution is not allowed.
<b>Massachusetts</b>	Expressly indicate "No Substitution."
<b>Michigan</b>	Indicate in own handwriting "Dispense as Written" or "DAW." Expressly indicates that prescription is to be dispensed as communicated for prescriptions other than those written.
<b>Minnesota</b>	Indicate in own handwriting "Dispense as Written" or "DAW," unless the prescription is transmitted electronically, in accordance with the Code of Federal Regulations title 42, section 423.
<b>Mississippi</b>	Sign on the appropriate line of the prescription.
<b>Missouri</b>	If a prescriber orders by any means that a brand-name drug must be dispensed, then no drug selection is permitted.
<b>Montana</b>	Handwrite "Brand Name Medically Necessary." Can be printed if electronically generated.
<b>Nebraska</b>	Expressly indicate brand name in some manner.
<b>Nevada</b>	Handwrite "Dispense as Written" or "DAW."
<b>New Hampshire</b>	Handwrite "Medically Necessary" on each paper prescription or use electronic indications when transmitted digitally. In addition, give instructions when transmitted orally that the brand is "Medically Necessary."

<b>STATE</b>	<b>ON EACH PRESCRIPTION</b>
<b>New Jersey</b>	Sign on the appropriate line of the prescription.
<b>New Mexico</b>	Handwrite “No Substitution” or abbreviate “No Sub” on the face of the prescription.
<b>New York</b>	Indicate “Dispense as Written” in the designated box or positive indication of the brand for electronic prescriptions. Handwrite “Brand Medically Necessary” on the face of the prescription for Medicaid patients or product selection is allowed.
<b>North Carolina</b>	Expressly indicate in some manner that substitution is not allowed. Sign on the appropriate line of the prescription.
<b>North Dakota</b>	Indicate in own handwriting “Brand Medically Necessary” and sign. Expressly indicate in some manner that substitution is not allowed.
<b>Ohio</b>	In case of written or electronic prescription, including computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription “dispense as written,” “DAW,” “do not substitute,” “brand medically necessary,” or any other numerical code that indicates the prescriber’s intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designated procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.
<b>Oklahoma</b>	Under state law, pharmacies must dispense the prescriber’s choice. The patient or the prescriber can authorize a generic substitution
<b>Oregon</b>	Write, telephone, or electronically transmit that there shall be no substitution for the branded drug in any prescription. For an electronically transmitted prescription, the prescriber or the prescriber’s agent shall clearly indicate substitution instructions in the prescription drug order as well as all the relevant electronic indicators sent as part of the electronic prescription transmission.
<b>Pennsylvania</b>	Handwrite and sign “Brand Necessary” or “Brand Medically Necessary.”
<b>Puerto Rico</b>	Must write on the face of the prescription, use own handwriting in writing the phrase, “Do Not Interchange.”
<b>Rhode Island</b>	Indicate “Brand Necessary” or “Brand Medically Necessary” and sign. Patient must also request in writing that the brand name be dispensed.
<b>South Carolina</b>	Sign on the appropriate line of the prescription.
<b>South Dakota</b>	Must write in own handwriting “Brand Necessary,” and sign.
<b>Tennessee</b>	Use own handwriting including writing the prescription with the following language (but not limited to): “brand name medically necessary,” “dispense as written,” “medically necessary,” “brand name,” “no generic,”; or any abbreviation of the language in the section above; or any other prescriber handwritten notation such as circling a preprinted “dispense as written” on the prescription order, that clearly conveys the intent that a brand name is necessary for the patient.
<b>Texas</b>	Use own handwriting to write “Brand Necessary” or “Brand Medically Necessary” or product selection is allowed.
<b>Utah</b>	Expressly indicate the brand name in some manner. Use of preprinted “Do Not Substitute” checked box is allowed.
<b>Vermont</b>	Use own handwriting to write “Brand Necessary,” “No Substitution,” “Dispense as Written,” or “DAW.”
<b>Virginia</b>	Handwrite “Brand Medically Necessary” on the face of the prescription for Medicaid patients. For non-Medicaid patients, the phrase must be included but is not required to be handwritten.
<b>Washington</b>	Sign on the appropriate line of the prescription.
<b>West Virginia</b>	Expressly indicate in some manner that substitution is not allowed. Must indicate by using own handwriting to write “Medically Necessary,” “Brand Necessary,” or “Brand Medically Necessary.”
<b>Wisconsin</b>	Expressly indicate the brand name in some manner.
<b>Wyoming</b>	Expressly indicate that substitution is not allowed.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide.

## INDICATION & IMPORTANT SAFETY INFORMATION FOR EMFLAZA® (DEFLAZACORT)

### INDICATION

EMFLAZA® is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

### IMPORTANT SAFETY INFORMATION

Contraindications: EMFLAZA is contraindicated in patients with a hypersensitivity to deflazacort or any of the inactive ingredients in EMFLAZA.

### Warnings & Precautions

- **Alterations in Endocrine Function:** Corticosteroids, such as EMFLAZA, can cause serious and life-threatening alterations in endocrine function, especially with chronic use. Monitor patients receiving EMFLAZA for Cushing's syndrome, hyperglycemia, and adrenal insufficiency after EMFLAZA withdrawal. In addition, patients with hypopituitarism, primary adrenal insufficiency or congenital adrenal hyperplasia, altered thyroid function, or pheochromocytoma may be at increased risk for adverse endocrine events. Acute adrenal insufficiency or "withdrawal syndrome" can occur if corticosteroids are withdrawn abruptly, and can be fatal. The risk is reduced by gradually tapering the corticosteroid dose when withdrawing treatment. During times of medical stress, corticosteroid dosage may need to be increased.
- **Immunosuppression and Increased Risk of Infection:** Increased risk of new, exacerbation, dissemination, or reactivation of latent infections, which can be severe and at times fatal; Signs and symptoms of infection may be masked. Tell patients and/or caregivers to inform their healthcare provider if the patient has had recent or ongoing infections or if they have recently received a vaccine. Warn patients who are on corticosteroids who have not had chickenpox or measles to avoid exposure to chickenpox or measles and to alert their healthcare provider immediately if they are exposed.
- **Alterations in Cardiovascular/Renal Function:** Monitor for elevated blood pressure. Dietary salt restriction and potassium supplementation may be needed.
- **Gastrointestinal Perforation:** Increased risk of gastrointestinal perforation during corticosteroid use in patients with certain gastrointestinal disorders such as active or latent peptic ulcers, diverticulitis, recent intestinal anastomoses, and inflammatory bowel disease. Signs and symptoms may be masked.
- **Behavioral and Mood Disturbances:** May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis. Encourage patients to seek medical attention if symptoms develop or worsen.

- **Effects on Bones:** The risk of osteoporosis increases with prolonged use of EMFLAZA, which can predispose patients to vertebral and long bone fractures. Monitor for decreases in bone density with chronic use of EMFLAZA.
- **Ophthalmic Effects:** May include cataract formation, ocular infections, and glaucoma. If treatment with corticosteroids, including EMFLAZA, are continued for more than 6 weeks, monitor intraocular pressure.
- **Vaccination:** Do not administer live or live attenuated vaccines to patients receiving immunosuppressive doses of corticosteroids. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting EMFLAZA.
- **Serious Skin Rashes:** Toxic epidermal necrolysis has been reported with the use of deflazacort. Discontinue at the first sign of rash, unless the rash is clearly not drug related.
- **Effects on Growth and Development:** Long-term use of corticosteroids, including EMFLAZA, may slow growth and development in children.
- **Thromboembolic Events:** Observational studies have shown an increased risk of thromboembolism. Use EMFLAZA with caution in patients who have or may be predisposed to thromboembolic disorders.

**Adverse Reactions:** The most common adverse reactions ( $\geq 10\%$  for EMFLAZA and greater than placebo) are Cushingoid appearance, weight increased, increased appetite, upper respiratory tract infection, cough, pollakiuria, hirsutism, central obesity, and nasopharyngitis.

**Drug Interactions:** Give one third of the recommended dose of EMFLAZA when EMFLAZA is administered with strong or moderate CYP3A4 inhibitors. Avoid use of strong or moderate CYP3A4 inducers with EMFLAZA, as they may reduce efficacy.

**Please see [www.emflaza.com](http://www.emflaza.com) for the full Prescribing Information.**

For medical information, product complaints, or to report an adverse event, please call **1-866-562-4620** or email at [usmedinfo@ptcbio.com](mailto:usmedinfo@ptcbio.com).

You may also report adverse events directly to FDA at **1-800-FDA-1088** or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).