

## Hikma launches Deflazacort Tablets in the US

**London, UK, 14 October 2026** – Hikma Pharmaceuticals PLC (Hikma, Group), a multinational pharmaceutical company, today announced the US launch of Deflazacort Tablets in four strengths (6mg, 18mg, 30mg, and 36mg), expanding its rare disease portfolio.

The product is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older. Please see Important Safety Information below and full Prescribing Information at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=00df3169-b8e3-4584-823b-91b71807d1a6>.

“Duchenne muscular dystrophy is a rare, progressive condition, and the families managing it depend on uninterrupted access to standard-of-care medicines,” said Hafrun Fridriksdottir, US President and Chief R&D Officer at Hikma. “This is our latest rare disease launch and reflects our ongoing focus on more complex products where reliable supply matters most. We are manufacturing Deflazacort Tablets in the US, at our state-of-the-art facility in Columbus, Ohio, and adding a further qualified, domestic supplier to this market helps support continuity for patients and their caregivers.”

According to IQVIA, US sales of Deflazacort Tablets were approximately \$25 million in the 12 months ending June 2026.

Hikma supplies a broad range of increasingly complex non-injectable products to the US market. Our Columbus, Ohio facility supports this portfolio, and we are committed to continued investment in US manufacturing.

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***This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.***

### About Hikma

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 9,400 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: [www.hikma.com](http://www.hikma.com)

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (LEI:549300BNS685UXH4JI75) (rated BBB/stable S&P and BBB/stable Fitch)

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## IMPORTANT SAFETY INFORMATION AND INDICATIONS FOR DEFLAZACORT TABLETS

### INDICATIONS

Deflazacort tablets are indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

### CONTRAINDICATIONS

Deflazacort tablets are contraindicated in patients with known hypersensitivity to deflazacort or to any of the inactive ingredients.

### WARNINGS AND PRECAUTIONS

- **Alterations in Endocrine Function**—Corticosteroids, such as deflazacort tablets, can cause serious and life-threatening alterations in endocrine function, especially with chronic use. Monitor patients for Cushing's syndrome, hyperglycemia and adrenal insufficiency after deflazacort tablets 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. Corticosteroids produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, with the potential for the development of secondary adrenal insufficiency after withdrawal of corticosteroid treatment. Acute adrenal insufficiency can occur if corticosteroids are withdrawn abruptly, and can be fatal. The degree and duration of adrenocortical insufficiency produced varies and depends on the dose, frequency and duration of corticosteroid therapy. The risk is reduced by gradually tapering the corticosteroid dose when withdrawing treatment. This insufficiency may persist, however, for months after discontinuation of prolonged therapy; therefore, in any situation of stress occurring during that period of discontinuation, corticosteroid therapy should be reinstituted. For patients already taking corticosteroids during times of stress, the dosage may need to be increased. A steroid "withdrawal syndrome," seemingly unrelated to adrenocortical insufficiency, may also occur following abrupt discontinuance of corticosteroids. Corticosteroids can increase blood glucose, worsen pre-existing diabetes, predispose those on long-term therapy to diabetes mellitus and may reduce the effect of anti-diabetic drugs. Metabolic clearance of corticosteroids is decreased in hypothyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate a dose adjustment of the corticosteroid. When concomitant administration of corticosteroids and levothyroxine is required, administration of corticosteroid should precede the initiation of levothyroxine therapy to reduce the risk of adrenal crisis. There have been reports of pheochromocytoma crisis, which can be fatal, after administration of systemic corticosteroids. In patients with suspected or identified pheochromocytoma, consider the risk of pheochromocytoma prior to administering corticosteroids.
- **Immunosuppression and Increased Risk of Infection**—Corticosteroids can reduce resistance to new infections, exacerbate existing infections, increase the risk of disseminated infections, increase the risk of reactivation or exacerbation of latent infections or mask some signs of infection. Corticosteroid-associated infections can be mild but can be severe, and at times fatal. The rate of infectious complications increases with increasing corticosteroid dosages. Monitor for the development of infection and consider deflazacort tablets withdrawal or dosage reduction as needed. If deflazacort tablets are used to treat a condition in patients with latent tuberculosis or tuberculin reactivity, reactivation of tuberculosis may occur. Closely monitor such patients for reactivation. During prolonged deflazacort tablets therapy, patients with latent tuberculosis or tuberculin reactivity should receive chemoprophylaxis. Varicella and measles can have a serious or even fatal course in non-immune patients taking corticosteroids, including deflazacort tablets; particular care should be taken to avoid exposure to varicella and measles. Hepatitis B virus reactivation can occur in patients who are hepatitis B carriers treated with immunosuppressive dosages of corticosteroids, including deflazacort tablets. Reactivation can also occur infrequently in corticosteroid-treated patients who appear to have resolved hepatitis B infection. Screen patients for hepatitis B infection before initiating immunosuppressive treatment with deflazacort tablets. Corticosteroids, including deflazacort tablets, may exacerbate systemic fungal infections; therefore, avoid deflazacort tablets use in the presence of such infections unless deflazacort tablets is needed to control drug reactions. For patients on deflazacort tablets who develop systemic fungal infections, deflazacort tablets withdrawal or dose reduction is recommended. Corticosteroids, including deflazacort tablets, may activate latent amebiasis. Therefore, it is recommended that latent amebiasis or active amebiasis be ruled out before initiating deflazacort tablets in patients who have spent time in the tropics or patients with unexplained diarrhea. Corticosteroids, including deflazacort tablets, should be used with great care in patients with known or suspected *Strongyloides* (threadworm) infestation. Corticosteroid-induced immunosuppression may lead to *Strongyloides* hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia. Avoid corticosteroids,

including deflazacort tablets, in patients with cerebral malaria.

- **Alteration in Cardiovascular/Renal Function**—Monitor blood pressure and assess for signs and symptoms of volume overload. Monitor serum potassium levels. Dietary salt restriction and potassium supplementation may be necessary. Use deflazacort tablets with caution in patients with congestive heart failure, hypertension or renal insufficiency. Literature reports suggest an association between corticosteroid use and left ventricular free wall rupture after a recent myocardial infarction; therefore, deflazacort tablets should be used with great caution in these patients.
- **Gastrointestinal Perforation**—There is an increased risk of gastrointestinal perforation during corticosteroid use in patients with certain gastrointestinal disorders such as active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses and non-specific ulcerative colitis. Signs of gastrointestinal perforation may be masked. Avoid corticosteroids if there is a probability of impending perforation, abscess or other pyogenic infections; diverticulitis; fresh intestinal anastomoses or active or latent peptic ulcer.
- **Behavioral or Mood Disturbances**—Potentially severe psychiatric adverse reactions may occur with systemic corticosteroids, including deflazacort tablets. Symptoms typically emerge within a few days or weeks of starting treatment and may be dose-related. Psychiatric reactions usually involve hypomanic or manic symptoms during treatment and depressive episodes after discontinuation of treatment. Inform patients or caregivers and encourage them to seek medical attention if psychiatric symptoms develop, especially if depressed mood or suicidal ideation is suspected.
- **Effects on Bones**—Corticosteroids, including deflazacort tablets, have the potential to cause inhibition of bone growth in pediatric patients and the development of bone loss at any age. Bone loss can predispose patients to vertebral and long bone fractures. Consider a patient's risk of osteoporosis before initiating corticosteroid therapy. Monitor bone mineral density in patients on long-term treatment with deflazacort tablets. Corticosteroids, including deflazacort tablets, may cause avascular necrosis.
- **Ophthalmic Effects**—Corticosteroids, including deflazacort tablets, may produce posterior subcapsular cataracts. Corticosteroids may also cause glaucoma with possible damage to the optic nerves, and may increase the risk of secondary ocular infections caused by bacteria, fungi or viruses. Corticosteroids are not recommended for patients with active ocular herpes simplex. Monitor intraocular pressure if treatment with deflazacort tablets is continued for more than 6 weeks.
- **Immunizations**—Administer all immunizations according to immunization guidelines prior to starting deflazacort tablets. Administer live-attenuated or live vaccines at least 4 to 6 weeks prior to starting deflazacort tablets. Patients on deflazacort tablets may receive concurrent vaccinations, except for live-attenuated or live vaccines.
- **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 deflazacort tablets, can have negative effects on growth and development in children.
- **Myopathy**—Patients receiving corticosteroids, including deflazacort tablets, and concomitant therapy with neuromuscular blocking agents or patients with disorders of neuromuscular transmission may be at increased risk of developing acute myopathy.
- **Kaposi's Sarcoma**—Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions.
- **Thromboembolic Events**—Observational studies have shown an increased risk of thromboembolism particularly with higher cumulative doses of corticosteroids. Use deflazacort tablets with caution in patients who have or may be predisposed to thromboembolic disorders.
- **Anaphylaxis**—Rare instances of anaphylaxis have occurred in patients receiving corticosteroid therapy, including deflazacort tablets.

## ADVERSE REACTIONS

Serious adverse reactions are described in the Warnings and Precautions section, above, and in the [Full Prescribing Information](#) for deflazacort tablets.

### **Clinical Trials Experience**

Adverse reactions occurring in >5% of DMD patients treated with deflazacort 0.9 mg/kg/day at 12 weeks included Cushingoid appearance, weight increased, increased appetite, upper respiratory tract infection, cough, pollakiuria, nasopharyngitis, hirsutism, central obesity, erythema, irritability, rhinorrhea and abdominal discomfort.

### **DRUG INTERACTIONS**

Give one-third the recommended dosage of deflazacort tablets when moderate or strong CYP3A4 inhibitors (e.g., clarithromycin, fluconazole, diltiazem, verapamil, grapefruit juice) are used concomitantly with deflazacort tablets. Avoid concomitant use of strong or moderate CYP3A4 inducers with deflazacort tablets, as they may reduce efficacy. Patients receiving corticosteroids, including deflazacort tablets, and concomitant therapy with neuromuscular blocking drugs may be at increased risk of developing an acute myopathy.

### **USE IN SPECIFIC POPULATIONS**

- **Pregnancy**—Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism. Corticosteroids, including deflazacort tablets, readily cross the placenta.
- **Lactation**—Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production or cause other untoward effects. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for deflazacort tablets and any potential adverse effects on the breastfed infant.
- **Pediatric Use**—Safety and effectiveness in pediatric patients below the age of 2 years have not been established.
- **Hepatic Impairment**—There is no clinical experience in patients with severe hepatic impairment and a dosing recommendation cannot be provided for these patients.

For more information, please see the [Full Prescribing Information](#) for deflazacort tablets.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <https://www.fda.gov/medwatch> or call 1-800-FDA-1088.

For more information about deflazacort tablets, please contact Hikma Pharmaceuticals USA Inc. 1-800-962-8364.

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