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Novel Drug Approvals 2023

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INTRODUCTION

This article provides an overview of the novel drugs approved for 2023.1 The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) provides standards to drug developers. The CDER sets standards for required data needed in the drug development and application process. Every year a variety of new drugs and biological products are approved. Some are new molecular compounds while others are structurally similar to those already on the market. Therefore, products may not have been used in medical practice previously while others have already been used in practice. This article highlights medications that are new in medical practice over the last year and bring attention to the numerous advancements in medicine. From January 1, 2023, to December 6, 2023, the FDA has approved fifty-three novel drugs highlighted in Table 1. Hematology and Oncology accounted for the majority of drug approvals. Four medications are discussed in detail based on their use in the outpatient setting.

Table 1. Novel DrugApprovals for 2023[1]

	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date
Autoimmune	Omvoh	mirikizumab-mrkz	10/26/2023	To treat ulcerative colitis
	Bimzelx	bimekizumab	10/17/2023	To treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
	Zilbrysq	zilucoplan	10/17/2023	To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive
	Velsipity	etrasimod	10/12/2023	To treat moderately to severely active ulcerative colitis in adults
	Rystiggo	rozanolixizumab-noli	6/26/2023	To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor- or anti-muscle-specific tyrosine kinase antibody-positive
Cardiology	Inpefa	sotagliflozin	5/26/2023	To treat heart failure
Endocrine	Ngenla	somatrogon-ghla	6/27/2023	To treat growth failure due to inadequate secretion of endogenous growth hormone
	Veozah	fezolinetant	5/12/2023	To treat moderate to severe hot flashes caused by menopause
	Brenzavvy	bexagliflozin	1/20/2023	To improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise
Genetic Conditions	Qalsody	tofersen	4/25/2023	To treat amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation
	Joenja	leniolisib	3/24/2023	To treat activated phosphoinositide 3-kinase delta syndrome
	Elfabrio	pegunigalsidase alfa-iwxj	5/9/2023	To treat confirmed Fabry disease
	Agamree	vamorolone	10/26/2023	To treat Duchenne muscular dystrophy
	Daybue	trofinetide	3/10/2023	To treat Rett syndrome
	Veopoz	pozelimab-bbfg	8/18/2023	To treat patients 1 year old and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease

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Table 1. Continued

	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date
Hematology & Oncology	Fabhalta	iptacopan	12/5/2023	To treat paroxysmal nocturnal hemoglobinuria
	Ogsiveo	nirogacestat	11/27/2023	To treat adults with progressing desmoid tumors who require systemic treatment
	Truqap	capivasertib	11/16/2023	To treat breast cancer that meets certain disease criteria
	Ryzneuta	efbemalenograstim alfa-vuxw	11/16/2023	To treat neutropenia
	Augtyro	repotrectinib	11/15/2023	To treat ROS1-positive non-small cell lung cancer
	Fruzaqla	fruquintinib	11/8/2023	To treat refractory, metastatic colorectal cancer
	Loqtorzi	toripalimab-tpzi	10/27/2023	To treat recurrent or metastatic nasopharyngeal carcinoma when used together with or following other therapies
	Aphexda	motixafortide	9/8/2023	To use with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma
	Elrexfio	elranatamab-bcmm	8/14/2023	To treat adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy
	Talvey	talquetamab-tgvs	8/9/2023	To treat adults with relapsed or refractory multiple myeloma who have received at least four prior therapies
	Columvi	glofitamab-gxbm	6/15/2023	To treat diffuse large B-cell lymphoma, not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy
	Posluma	flotufolastat F 18	5/25/2023	To use with positron emission tomography imaging in certain patients with prostate cancer
	Epkinly	epcoritamab-bysp	5/19/2023	To treat relapsed or refractory diffuse large B-cell lymphoma (not otherwise specified) and high-grade B-cell lymphoma after two or more lines of systemic therapy
	Zynyz	retifanlimab-dlwr	3/22/2023	To treat metastatic or recurrent locally advanced Merkel cell carcinoma
	Jesduvroq	daprodustat	2/1/2023	To treat anemia caused by chronic kidney disease for adults on dialysis for at least four months
	Jaypirca	pirtobrutinib	1/27/2023	To treat relapsed or refractory mantle cell lymphoma in adults who have had at least two lines of systemic therapy, including a BTK inhibitor
	Vanflyta	quizartinib	7/20/2023	To use as part of a treatment regimen for newly diagnosed acute myeloid leukemia that meets certain criteria
	Ojjaara	momelotinib	9/15/2023	To treat intermediate or high-risk myelofibrosis in adults with anemia
	Orserdu	elacestrant	1/27/2023	To treat ER+, HER2-, ESR1 mutated, advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy
Infectious Disease	Defencath	taurolidine, heparin	11/15/2023	To reduce the incidence of catheter-related bloodstream infections in adults with receiving chronic hemodialysis through a central venous catheter
	Xacduro	sulbactam, durlobactam	5/23/2023	To treat HAP and VAP bacterial pneumonia caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex
	Rezzayo	rezafungin	3/22/2023	To treat candidemia and invasive candidiasis
	Beyfortus	nirsevimab-alip	7/17/2023	To prevent respiratory syncytial virus (RSV) lower respiratory tract disease
	Paxlovid	nirmatrelvir, ritonavir	5/25/2023	To treat mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19
Musculoskeletal	Sohonos	palovarotene	8/16/2023	To reduce the volume of new heterotopic ossification in patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva
	Pombiliti	cipaglucosidase alfa-atga	9/28/2023	To treat late-onset Pompe disease
Nephrology	Filspari	sparsentan	2/17/2023	To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression
	Rivfloza	nedosiran	9/29/2023	To lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function
Neurology & Psychiatric	Exxua	gepirone	9/22/2023	To treat major depressive disorder
	Zurzuvae	zuranolone	8/4/2023	To treat postpartum depression
	Leqembi	lecanemab-irmb	1/6/2023	To treat Alzheimer's disease
	Zavzpret	zavegepant	3/9/2023	To treat migraine
	Skyclarys	omaveloxolone	2/28/2023	To treat Friedrich's ataxia

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Table 1. Continued

	Drug Name	Active Ingredient	Approval Date	FDA-approved use on approval date
Ophthalmology	Xdemvy	lotilaner	7/25/2023	To treat Demodex blepharitis
	Izervay	avacincaptad pegol	8/4/2023	To treat geographic atrophy secondary to age-related macular degeneration
	Miebo	perfluorhexyloctane	5/18/2023	To treat signs and symptoms of dry eye disease
Miscellaneous	Lamzede	velmanase alfa-tycv	2/16/2023	To treat non-central nervous system manifestations of alpha-mannosidosis
	Litfulo	ritlecitinib	6/23/2023	To treat severely patchy hair loss

INPEFA® (SOTAGLIFLOZIN)

Sodium-glucose cotransporter 2 (SGLT2) inhibitors reduce the risk of hospitalizations for heart failure or death from cardiovascular causes among patients with stable heart failure.[2] The 2022 AHA/ACC/HFSA Joint Guideline recommends that SGLT2 inhibitors be used as first-line agents for guideline directed medication therapy (GDMT) for Heart Failure with reduced Ejection Fraction (HFrEF) (class 1A recommendation). Moreover, the guideline recommends that SGLT2 inhibitors be initiated prior to discharge for patients with HFrEF and states that GDMT optimalization is a critical part of a transition of care plan in heart failure patients.

The 2023 American College of Cardiology Expert Consensus recommends SGLT2 inhibitors as the foundational therapy for HFpEF.[3]

Sotagliflozin (Lexicon Pharmaceuticals Inc., Bridgewater, New Jersey) is a newly approved SGLT2 inhibitor indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors. It is an inhibitor of SGLT2 and SGLT1. Inhibiting SGLT2 reduces renal reabsorption of glucose and sodium which may influence physiological functions such as lowering both pre- and afterload of the heart and downregulating sympathetic activity. Inhibiting SGLT1 provides a small reduction of intestinal absorption of glucose and sodium and causes an acute and sustained release of GLP-1 which leads to minor enhanced glycemic control. The decreased glucose and sodium absorption may be related to a recognized reported side effect of diarrhea. The mechanism of sotagliflozin providing cardiovascular benefits has not been established.[4]

The SOLOIST-WHF study was a multi-center, randomized, double-blind, placebo-controlled, phase 3 study in patients with type 2 diabetes who had been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure (N=1,222). The study evaluated heart failure outcomes and safety of sotagliflozin (n=608) versus placebo (n=614) when added to standard of care. Sotagliflozin showed a 33% relative risk reduction in the primary endpoint of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits (HR 0.67, 95% CI: 0.53, 0.85, p=0.001). The absolute risk reduction was 0.25 with the number needed to treat to prevent 1 primary composite event of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit being 4.2A post hoc analysis initiated on or before discharge showed >50% reduction in readmissions for heart failure related event or cardiovascular death in 30 days (HR 0.49, 95% CI: 0.27, 0.91).

Within SOLOIST-WHF, the most common adverse events in the study group versus placebo included urinary tract infections (8.6% vs 7.2%), volume depletion (9.3% vs 8.8%), diarrhea (6.9% vs 4.1%), hypoglycemia (4.3% vs 2.8%), and dizziness (2.6% vs 2.5%).[2] The number needed to harm was 50, which was not clinically significant as there were no more serious events due to drug intervention than in the placebo group.

Sotagliflozin is contraindicated in patients with a history of hypersensitivity to sotagliflozin. Adverse reactions noted in sotagliflozin use include diabetic ketoacidosis, volume depletion, urosepsis and pyelonephritis, hypoglycemia with concomitant use with insulin secretagogues, and genital mycotic infections. Due to the increased risk of diabetic ketoacidosis with SGLT2 inhibitor use, patients with type 1 diabetes, type 2 diabetes, and pancreatic disorders should have ketones monitored. Volume status of patients should be monitored in patients due to volume depletion associated with SGLT2 inhibitor utilization.4

Dosage and administration: 200 mg by mouth once daily initially and then titrate to 400 mg by mouth once daily as tolerated. Ensure corrected volume status prior to initiating. In patients with decompensated heart failure, initiate sotagliflozin once hemodynamically stable. Withhold sotagliflozin for 3 days prior to major surgery or procedures when prolonged fasting is expected.[4]

ZURZUVAE (ZURANOLONE)

Background

Postpartum depression (PPD) is a major depressive episode that usually occurs after childbirth but can sometimes start during the later stages of pregnancy.[7] PPD can cause women to feel sad, guilty, and worthless. In severe cases, women with PPD may have thoughts of harming themselves or even their child. Like other forms of depression, PPD can also cause loss of interest, cognitive impairment, and lack of energy. The negative effects of PPD on women can result in detrimental effects on their child's development as well.[7]

On August 4, 2023, the United States Food and Drug Administration (FDA) approved zuranolone, brand name Zurzuvae (Biogen Inc., Cambridge, MA), the first oral medication used to treat PPD in adults.[7] Before the approval of zuranolone, the only treatment that was available to treat PPD was an intravenous injection that had to be given by a healthcare provider.[7] Zuranolone is thought to work by modulating gamma-aminobutyric acid (GABA) A receptors.[8]

Clinical Trials

The efficacy and safety of zuranolone for PPD treatment has been studied in two randomized, placebo-controlled, double-blind, multicenter studies (Study 1 and Study 2).[8] Both studies included women who met the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for a major depressive episode with symptom onset in the third trimester or within four weeks of delivery who had a baseline Hamilton Rating Scale for Depression (HAMD-17) score of 26 or higher.[8] The HAMD-17 is a clinical assessment tool used to rate the severity of depression in patients.[19] A HAMD-17 score is calculated by rating patients on 17 items, including suicidality, depressed mood, insomnia, anxiety, and feelings of guilt.[19] A score of 0 to 7 is normal, while a score of 23 or higher indicates very severe depression.[19]

In Study 1, patients received 50 mg of zuranolone (N=98) or placebo (N=97) once daily in the evening with fat-containing food for 14 days, with the option to reduce to 40 mg once daily based on tolerability.[5] In Study 2, patients received another zuranolone capsule formulation (approximately equivalent to 40 mg of zuranolone) (N=76) or placebo (N=74) once daily in the evening with food for 14 days.[6] Patients were followed for at least four weeks after the 14 days of treatment.[8]

The primary efficacy endpoint for both studies was the change from baseline in depressive symptoms at Day 15, measured by the HAMD-17 score.[8] In both studies, patients in the zuranolone group had statistically significantly greater improvement in depressive symptoms compared to placebo.[8] In Study 1, the zuranolone group had a least squares (LS) mean change from baseline of -15.6 compared to -11.6 in the placebo group, with a difference of -4 (95% confidence interval -6.3, -1.7).[5] In Study 2, the zuranolone group had a LS mean change from baseline of -17.8 compared to -13.6 in the placebo group, with a difference of -4.2 (95% confidence interval -6.9, -1.5).[6]

In Study 1, the incidence of adverse reactions that led to discontinuation in the zuranolone and placebo groups was 2% and 1%, respectively.5 In Study 2, the incidence was 1% and 0%, respectively.[6] For both studies, the most common adverse reaction leading to treatment discontinuation in the zuranolone group was somnolence.8 In Study 1, dosage reduction due to an adverse reaction occurred in 14% of zuranolone-treated patients, with the most common adverse reactions being somnolence and dizziness.[5] In Study 2, dosage reduction due to an adverse reaction occurred in 4% of zuranolone-treated patients, with the most common adverse reactions being somnolence and confusional state.[6]

Prescribing Information

Zuranolone is a Schedule IV federal controlled substance due to its potential to be abused and its potential for physical dependence.[8] It has a boxed warning for driving impairment due to central nervous system (CNS) depressant effects.[8] Patients taking zuranolone should not drive or engage in other potentially hazardous activities for at least 12 hours after taking zuranolone.[8] Zuranolone may also cause suicidal thoughts and behavior as well as fetal harm.[8] The most common side effects of zuranolone include somnolence, dizziness, diarrhea, nasopharyngitis, urinary tract infection, and fatigue.[8]

Zuranolone is available as 20 mg, 25 mg, and 30 mg oral capsules.[8] The recommended dosage is 50 mg by mouth once daily in the evening for 14 days, taken with fat-containing food for adequate absorption.8 The dosage may be reduced to 40 mg if the patient experiences CNS depressant effects.[8] The dosage may be reduced to 30 mg if the patient is also taking a strong CYP3A4 inhibitor, such as clarithromycin, ritonavir, and azole antifungals like itraconazole and ketoconazole, or if the patient has severe hepatic impairment or moderate or severe renal impairment.[8] Use of zuranolone should be avoided with concomitant CYP3A4 inducers, like phenytoin, phenobarbital, and rifampin.[8]

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JESDUVROQ (DAPRODUSTAT)

Background

Roughly 15% of adults in the United States (US) are estimated to have chronic kidney disease (CKD).[9] The progressive nature of CKD causes patients to experience a decreased quality of life due to the increased risk of many complications, including anemia. As glomerular filtration rate (GFR) decreases, patients with CKD have a gradual decline in hemoglobin (Hb) concentration.[10] The cause of which is most commonly due to lack of endogenous erythropoietin (EPO).[11] Patients are deemed anemic if they have a Hb concentration of <13 g/dL in males or <12 g/dL in females. For anemic patients with adequate nutritional stores or who remain anemic despite supplementation, erythropoietin stimulating agents (ESA) such as epoetin alfa and darbepoetin are used. ESAs benefit those on dialysis by controlling anemia and reducing the need for blood transfusions.[12] However, ESAs are administered subcutaneous (SQ) or intravenous (IV), which is unattractive to some patients who would prefer oral therapy. After nearly 35 years of parenteral ESAs being the only option for these patients, there is now an oral option available.

In February 2023, daprodustat, (GlaxoSmtihKline, Brentford, Middlesex, United Kingdom), was approved by the FDA for the treatment of anemia due to CKD in adults who have been receiving dialysis for at least four months. Daprodustat is an oral small molecule inhibitor of hypoxia-inducible factor prolyl hydroxylase (PHD) which prevents degradation of hypoxia-inducible factor (HIF). HIF promotes endogenous EPO production, which is often the cause of anemia in CKD.[13]

Clinical Trials

Used for the basis of FDA approval, the Anemia Studies in Chronic Kidney Disease: Erythropoiesis Via a Novel Prolyl Hydroxylase Inhibitor Daprodustat–Dialysis (ASCEND-D) trial assessed the safety and efficacy of daprodustat.[14] The ASCEND-D trial was a randomized, open-label, phase 3 trial that included 2964 patients across 431 centers in 35 countries. Patients included in the trial had to have been undergoing dialysis for at least 90 days, had received an ESA for at least 6 weeks, had a Hb level of 8-12 g/dL, and had adequate iron stores. Key exclusion criteria included anemia unrelated to CKD, a recent cardiovascular event, or current or recent cancer. Patients were randomized to one of two treatment groups: daprodustat or an injectable ESA (IV epoetin alfa or SQ darbepoetin alfa). Initial doses of daprodustat (4-12 mg) were selected based on previous ESA dose(s) and were adjusted anywhere from 1-24 mg as needed to maintain a Hb range of 10-11 g/dL. The patients were evaluated at least every 4 weeks for the first year and at least every 12 weeks thereafter. The two primary outcomes were the mean change in the Hb level from baseline to the average during weeks 28-52 and the first occurrence of a major cardiovascular event (MACE). Mean change in Hb from baseline to 28-52 weeks was 0.28 ± 0.02 g/dL in the daprodustat group and 0.10 ± 0.02 g/dL in the ESA group (difference, 0.18 g/dL; 95% confidence interval [CI], 0.12 to 0.24). A MACE occurred in 25.2% (374 of 1487) of patients in the daprodustat group and in 26.7% (394 of 1477) of patients in the ESA group (hazard ratio, 0.93; 95% CI, 0.81 to 1.07). Both primary outcomes met noninferiority criteria, concluding that oral daprodustat was noninferior to parenteral ESAs in terms of change in Hb concentration from baseline and occurrences of MACEs.[14]

Prescribing information

Daprodustat is indicated for adults with anemia due to CKD who have been on dialysis for at least four months. It is taken once daily without regard to food, iron, phosphate binders, or dialysis. The dose of daprodustat should be individualized so that patients receive the lowest dose possible that reduces the need for red blood cell transfusions. Daprodustat is available in 1, 2, 4, 6, 8, 12, 16, and 24 mg tablets, with a maximum dose of 24 mg once daily. Starting doses can be found in the table below in table 12 and table 2 3. Doses should be adjusted for those with moderate hepatic impairment (Child-Pugh Class B) and those who take moderate CYP2C8 inhibitors. For moderate hepatic impairment, starting doses should be reduced by half, unless the starting dose is 1 mg. Use is not recommended in patients with severe hepatic impairment (Child-Pugh Class C). For patients taking clopidogrel or moderate CYP2C8 inhibitors, starting doses should also be reduced by half, except in those whose starting dose is 1 mg.[13]

Table 2. Starting Dose for Adults not Receiving an ESA

Pre-Treatment Hb Level (g/dL)	Starting Dose of Daprodustat (once daily)
<9	4 mg
>9 to <10	2 mg
>10	1 mg

Table 3. Starting Dose for Adults Switching from an ESA

Epoetin Alfa IV (units/week)	Darbepoetin Alfa SQ/IV (mcg/4 weeks)	Methoxy PEG-Epoetin Beta SQ/IV (mcg/month)	Once Daily
≤2,000	20 to 30	30 to 40	4 mg
>2,000 to <10,000	>30 to ≤150	>40 to ≤180	6 mg
≥10,000 to <20,000	>150 to ≤300	>180 to ≤360	8 mg
≥20,000	>300	>360	12 mg

After initiation and each dose adjustment, Hb should be monitored every 2 weeks for the first month and then every 4 weeks thereafter. Similarly to ESAs, targeting a Hb concentration greater than 11 g/dL is not appropriate. Recommendations for dose adjustment based on Hb level can be found in the package insert. If a dose adjustment is required, doses should only be increased or decreased by one dose level at a time. If Hb levels do not increase in a clinically significant manner by week 24 of therapy, daprodustat should not be continued.[13]

Daprodustat carries a boxed warning for increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access. Therefore, use should be avoided in patients who have experienced one of these events within the past three months. The most common adverse reactions reported in clinical trials were hypertension (16%), diarrhea (11%), and headache (8%). Some patients experienced other serious effects such as hospitalization due to heart failure (28.6%), gastrointestinal erosions (%), and malignancy (3.2%).[14]

There is limited data regarding daprodustat use in pregnancy, lactation, and pediatrics. However, if a patient is breastfeeding, they should withhold from doing so while taking daprodustat and for one week after discontinuation. As for the geriatric population, 43% of patients in the ASCEND-D trial were 65 years or older and there were no differences in safety and efficacy reported.[13]

LITFULO (RITLECITINIB)

Background

Ritlecitinib is the generic name for the brand Litfulo (Pfizer, New York, New York) which has an FDA-approved indication for severe alopecia areata in adults and adolescents at least twelve years old. Alopecia areata is an autoimmune disease and approximately 7 million people in the United States have been diagnosed.[15] There are several different classifications based off the location and amount of hair loss.

Clinical Trials[16]

A randomized, doble-blind clinical trial in patients twelve years and older with alopecia areata with at least 50% scalp hair loss were studied for the safety and efficacy of Litfulo. Patients at baseline had abnormal eyebrows (83%) and eyelashes (75%). Scalp hair loss was assessed using the mean baseline Severity of Alopecia Tool (SALT) score.16 The SALT score is given as a percentage, the lower the score percent, the less hair loss occured.

A total of 718 patients were randomized to one of seven treatment groups for 48 weeks to evaluate recommended dose, safety, and efficacy. At week 24, when comparing Litfulo 50 mg every day (N=130) to placebo (N=131) a greater proportion of subjects had a SALT ≤ 10 compared to SALT ≤ 20 in treatment group. The SALT score is interpreted as a SALT ≤ 10 patients had 10% or less of scalp hair loss. The proportion of patients with a SALT ≤ 20 in treatment compared to placebo was 23.0% and 1.6% respectively (CI 13.4, 29.5). The proportion of patients with a SALT ≤ 10 in treatment compared to placebo was 13.4% and 1.5% respectively (CI 5.4, 18.3).

Prescribing Information

Litfulo is not indicated in women who are breastfeeding, patients with severe hepatic impairment, or in patients who need to receive live vaccinations.[17] This medication is administered as a 50 mg capsule to be taken orally once daily with or without food and is meant for long-term treatment. Litfulo should be swallowed whole and should not be crushed, chewed, or split. If a dose is missed, instruct patients to administer missed dose as soon as possible.[18] If it is less than eight hours before the next dose the dose should be skipped, then the regular schedule should be resumed. Common adverse effects to counsel patients on include headache, dizziness, and dermatologic effects such as acne vulgaris or skin rash. Less common, but serious adverse effects include risk of infections, malignancies, thrombosis, and mortality due to

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cardiovascular effects. Patients can expect to see the initial onset of medication results within four to eight weeks from starting the course of therapy. If for some reason patients need to interrupt therapy, interruption for less than six weeks will not result in significant loss of regrown hair.

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