

JESDUVROQ- daprodustat tablet, film coated

GlaxoSmithKline LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use JESDUVROQ safely and effectively. See full prescribing information for JESDUVROQ.

JESDUVROQ (daprodustat) tablets, for oral use
Initial U.S. Approval: 2023

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS

See full prescribing information for complete boxed warning.

- JESDUVROQ increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE). (5.1)
- Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels. (5.1)
- No trial has identified a hemoglobin target level, dose of JESDUVROQ, or dosing strategy that does not increase these risks. (2.4)
- Use the lowest dose of JESDUVROQ sufficient to reduce the need for red blood cell transfusions. (2.4)

INDICATIONS AND USAGE

JESDUVROQ is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months. (1)

Limitations of Use

Not shown to improve quality of life, fatigue, or patient well-being.

Not indicated for use:

- As a substitute for transfusion in patients requiring immediate correction of anemia.
- In patients not on dialysis.

DOSAGE AND ADMINISTRATION

- Administer orally once daily, with or without food. (2.2, 2.3)
- See Full Prescribing Information for starting dosage based on hemoglobin level, liver function and concomitant medications, and for dose titration and monitoring recommendations. (2.3, 2.4, 2.5, 2.6)

DOSAGE FORMS AND STRENGTHS

Tablets: 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg. (3)

CONTRAINDICATIONS

- Strong cytochrome P450 2C8 (CYP2C8) inhibitors such as gemfibrozil. (4)
- Uncontrolled hypertension. (4)

WARNINGS AND PRECAUTIONS

- Risk of Hospitalization for Heart Failure: Increased in patients with a history of heart failure. (5.2)
- Hypertension: Worsening hypertension, including hypertensive crisis may occur. Monitor blood pressure. Adjust anti-hypertensive therapy as needed. (5.3)
- Gastrointestinal Erosion: Gastric or esophageal erosions and gastrointestinal bleeding have been reported. (5.4)
- Not indicated for treatment of anemia of CKD in patients who are not dialysis-dependent (5.5)
- Malignancy: May have unfavorable effects on cancer growth. Not recommended if active malignancy. (5.6)

-----**ADVERSE REACTIONS**-----

Most common adverse reactions (incidence $\geq 10\%$) are hypertension, thrombotic vascular events, and abdominal pain. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----**DRUG INTERACTIONS**-----

- Moderate CYP2C8 Inhibitors: Reduce starting dose. (7.1)
- CYP2C8 Inducers: Monitor hemoglobin and adjust the dose of JESDUVROQ as appropriate. (7.2)

-----**USE IN SPECIFIC POPULATIONS**-----

- Pregnancy: May cause fetal harm. (8.1)
- Lactation: Breastfeeding not recommended until one week after the final dose. (8.2)
- Hepatic Impairment: Reduce the starting dose in patients with moderate hepatic impairment (Child-Pugh Class B). JESDUVROQ not recommended in severe hepatic impairment (Child-Pugh Class C). (8.6)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 8/2023

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FULL PRESCRIBING INFORMATION

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS

JESDUVROQ increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE) [see Warnings and Precautions (5.1)].

Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels [see Warnings and Precautions (5.1)].

No trial has identified a hemoglobin target level, dose of JESDUVROQ, or dosing strategy that does not increase these risks [see Dosage and Administration (2.4)].

Use the lowest dose of JESDUVROQ sufficient to reduce the need for red blood cell transfusions [see Dosage and Administration (2.4)].

1 INDICATIONS AND USAGE

JESDUVROQ is indicated for the treatment of anemia due to chronic kidney disease

(CKD) in adults who have been receiving dialysis for at least four months.

Limitations of Use

JESDUVROQ has not been shown to improve quality of life, fatigue, or patient well-being.

JESDUVROQ is not indicated for use:

- As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
- For treatment of anemia of chronic kidney disease in patients who are not on dialysis.

2 DOSAGE AND ADMINISTRATION

2.1 Pre-Treatment and On-Treatment Evaluations of Anemia, Iron Stores, and Liver Tests

Evaluation of Anemia and Iron Stores

Correct and exclude other causes of anemia (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding) before initiating JESDUVROQ. Evaluate the iron status in all patients before and during treatment with JESDUVROQ. Administer supplemental iron therapy when serum ferritin is less than 100 ng/ml or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course of therapy.

Liver Testing

Assess serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and total bilirubin prior to initiation of JESDUVROQ. Repeat the liver tests if the patient develops signs or symptoms that could be consistent with liver disease during treatment with JESDUVROQ.

2.2 Important Dosing Information

Individualize dosing and use the lowest dose of JESDUVROQ sufficient to reduce the need for red blood cell transfusions. Do not target a hemoglobin higher than 11 g/dL.

JESDUVROQ can be taken with or without food, and without regard to concomitant administration of iron or phosphate binders [see *Clinical Pharmacology (12.3)*].

JESDUVROQ should be swallowed whole. Tablets should not be cut, crushed, or chewed.

JESDUVROQ can be administered without regard to the timing or type of dialysis [see *Clinical Pharmacology (12.3)*].

If a dose of JESDUVROQ is missed, it should be taken as soon as possible, unless it is the same day as the next dose. In this case, the missed dose should be skipped, and the next dose taken at the usual time. Double-doses should not be taken to make-up for a missed dose.

2.3 Recommended Starting Dose of JESDUVROQ

Adults with Anemia Due to Chronic Kidney Disease Receiving Dialysis for at Least 4

Months

Adults Not Being Treated with an ESA: For adults not being treated with an ESA, the starting dose of JESDUVROQ is based on the hemoglobin level (see Table 1). Dose modifications are needed for patients receiving concomitant treatment with a moderate CYP2C8 inhibitor or moderate hepatic impairment [see *Dosage and Administration (2.5, 2.6), Drug Interactions (7.1), Use in Specific Populations (8.6), Clinical Pharmacology (12.3)*].

Table 1: Starting Dose of JESDUVROQ for Adults on Dialysis not Receiving an Erythropoiesis-Stimulating Agent

Pre-Treatment Hemoglobin Level (g/dL)	Starting Dose of JESDUVROQ (Once Daily Dosing)^a
<9	4 mg
≥9 to ≤10	2 mg
>10	1 mg

^a See dosing modifications in Section 2.5 if the patient has moderate hepatic impairment and Section 2.6 if the patient is on a moderate CYP2C8 inhibitor.

Adults Being Switched from an ESA: For adults being switched from an ESA to JESDUVROQ, the starting dose of JESDUVROQ is based on the dose regimen of the ESA at the time of substitution (see Table 2). Dose modifications are needed for patients receiving concomitant treatment with a moderate CYP2C8 inhibitor or moderate hepatic impairment [see *Dosage and Administration (2.5, 2.6), Drug Interactions (7.1), Use in Specific Populations (8.6), Clinical Pharmacology (12.3)*].

Table 2: Starting Dose of JESDUVROQ for Adults on Dialysis Switching from an Erythropoiesis-Stimulating Agent

Current Dose of ESA			Dose of JESDUVROQ^a
Epoetin Alfa^b Intravenous (units/week)	Darbepoetin Alfa Subcutaneous /Intravenous (mcg/4 weeks)	Methoxy PEG-Epoetin Beta Subcutaneous /Intravenous (mcg/month)	Once Daily Dosing
Less than or equal to 2,000	20 to 30	30 to 40	4 mg
Greater than 2,000 to less than 10,000	Greater than 30 to 150	Greater than 40 to 180	6 mg
Greater than or equal to 10,000 to less than 20,000	Greater than 150 to 300	Greater than 180 to 360	8 mg
Greater than or equal to 20,000	Greater than 300	Greater than 360	12 mg

ESA = Erythropoiesis stimulating agent.

^a See dosing modifications in Section 2.5 if the patient has moderate hepatic impairment and Section 2.6 if the patient is on a moderate CYP2C8 inhibitor.

^b For patients on subcutaneous epoetin alfa, convert the epoetin alfa subcutaneous dose to intravenous dose equivalent by multiplying the subcutaneous dose received per week by 1.42 to obtain the weekly intravenous dose.

2.4 Monitoring Response to Therapy and Dose Adjustment

Following initiation of therapy and after each dose adjustment, monitor hemoglobin every 2 weeks for the first month and then every 4 weeks thereafter.

When adjusting doses of JESDUVROQ, consider hemoglobin rate of rise, rate of decline and hemoglobin variability. Do not increase the dose of JESDUVROQ more frequently than once every 4 weeks.

- If the dose of JESDUVROQ needs to be adjusted, increase or decrease by one dose level at a time (see Table 3).
- Decrease the dose of JESDUVROQ if hemoglobin increases rapidly (e.g., greater than 1 g/dL over 2 weeks or greater than 2 g/dL over 4 weeks) or if the hemoglobin exceeds 11 g/dL.
- If hemoglobin exceeds 12 g/dL, interrupt treatment with JESDUVROQ. When the hemoglobin is within the target range, treatment may be restarted at one dose level lower (see Table 3).
- Treatment with JESDUVROQ should not be continued beyond 24 weeks of therapy if a clinically meaningful increase in hemoglobin level is not achieved. Alternative explanations for an inadequate response should be sought and treated before re-starting therapy.

Table 3: Dose Levels of JESDUVROQ

Daily dose of JESDUVROQ	1 mg	2 mg	4 mg	6 mg	8 mg	12 mg	16 mg	24 mg ^a
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^a 24 mg is the maximum recommended once daily dose.

2.5 Dosage Modification for Hepatic Impairment

Reduce the starting dose of JESDUVROQ by half (see Table 1 and Table 2) in patients with moderate hepatic impairment (Child-Pugh Class B) except in patients whose starting dose is already 1 mg.

Use of JESDUVROQ in patients with severe hepatic impairment (Child-Pugh Class C) is not recommended [see *Use in Specific Populations (8.6)*, *Clinical Pharmacology (12.3)*].

2.6 Dosage Modification for Concomitant Treatment with Moderate CYP2C8 Inhibitors

Reduce the starting dose of JESDUVROQ by half (see Table 1 and Table 2) in patients who are on clopidogrel or a moderate CYP2C8 inhibitor except in patients whose starting dose is already 1 mg [see *Drug Interactions (7.1)*, *Clinical Pharmacology (12.3)*].

Monitor hemoglobin and adjust the dose of JESDUVROQ when initiating or stopping

therapy with clopidogrel or a moderate CYP2C8 inhibitor during treatment with JESDUVROQ.

3 DOSAGE FORMS AND STRENGTHS

Tablets:

- 1 mg, gray, biconvex, round film-coated tablets debossed with “GS KF” on one face.
- 2 mg, yellow, biconvex, round film-coated tablets debossed with “GS V7” on one face.
- 4 mg, white, biconvex, round film-coated tablets debossed with “GS 13” on one face.
- 6 mg, pink, biconvex, round film-coated tablets debossed with “GS IM” on one face.
- 8 mg, orange, biconvex, round film-coated tablets debossed with “GS 5E” on one face.

4 CONTRAINDICATIONS

JESDUVROQ is contraindicated in patients:

- Receiving a strong CYP2C8 inhibitor such as gemfibrozil [*see Drug Interactions (7.1), Clinical Pharmacology (12.3)*].
- With uncontrolled hypertension [*see Warnings and Precautions (5.3)*].

5 WARNINGS AND PRECAUTIONS

5.1 Increased Risk of Death, Myocardial Infarction, Stroke, Venous Thromboembolism, and Thrombosis of Vascular Access

JESDUVROQ increases the risk of arterial and venous thrombotic events, that may be fatal, including myocardial infarction, stroke, venous thromboembolism and vascular access thrombosis [*see Boxed Warning, Adverse Reactions (6.1)*]. Patients with cardiovascular or cerebrovascular disease are at increased risk of these events. Avoid use in patients with a history of myocardial infarction, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting JESDUVROQ.

A rate of hemoglobin rise of greater than 1 g/dL over 2 weeks may contribute to these risks. Targeting a hemoglobin level of greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with ESAs, which also increase erythropoietin levels.

No trial has identified a hemoglobin target level, dose of JESDUVROQ, or dosing strategy that does not increase these risks. Use the lowest dose of JESDUVROQ sufficient to reduce the need for red blood transfusions. Adherence to dosing and hemoglobin monitoring recommendations is important to avoid excessive erythropoiesis [*see Dosage and Administration (2.4)*].

Advise patients to seek immediate medical attention if they develop signs or symptoms of myocardial infarction, stroke, venous thromboembolism, or thrombosis of vascular access. Evaluate and manage promptly if these occur.

5.2 Risk of Hospitalization for Heart Failure

In the ASCEND-D trial, hospitalization for heart failure was observed in 7.5% (3.3 per 100 Person Years [PY]) of patients on dialysis receiving JESDUVROQ and 6.8% (3.0 per 100 PY) of patients receiving recombinant human erythropoietin (rhEPO). Patients with a pre-existing history of heart failure were at increased risk of hospitalization for heart failure with JESDUVROQ (14.5%; 6.8 per 100 PY) compared to rhEPO (11.3%; 5.1 per 100 PY).

Consider the patient's history of heart failure when deciding whether to prescribe JESDUVROQ. Advise patients of the symptoms and signs of heart failure and to immediately report any worsening to their healthcare provider.

5.3 Hypertension

JESDUVROQ is contraindicated in patients with uncontrolled hypertension. In the ASCEND-D trial, worsening of hypertension occurred in 24% (12 per 100 PY) of patients receiving JESDUVROQ and 24% (12 per 100 PY) of patients receiving rhEPO [see *Adverse Reactions (6.1)*]. Serious worsening of hypertension occurred in 3.1% of patients receiving JESDUVROQ and 3.1% of patients receiving rhEPO. Cases of hypertensive crisis including hypertensive encephalopathy and seizures have also been reported in patients receiving JESDUVROQ. Periodically monitor blood pressure and adjust or initiate anti-hypertensive therapy as needed.

5.4 Gastrointestinal Erosion

In the ASCEND-D trial, gastric or esophageal erosions occurred in 5.7% (2.5 per 100 PY) of patients receiving JESDUVROQ and 6.6% (2.9 per 100 PY) of rhEPO-treated patients. Serious erosions, including gastrointestinal bleeding and the need for red blood cell transfusions, were reported in 3.6% and 3.1% of those receiving JESDUVROQ and rhEPO, respectively. Consider this risk particularly in patients at increased risk for gastrointestinal erosions, such as those with a history of gastrointestinal erosion, peptic ulcer disease, use of concomitant medications that increase the risk of gastrointestinal erosion, and current tobacco smokers and alcohol drinkers.

Advise patients of the symptoms and signs of gastric and esophageal erosions and of gastrointestinal bleeding and to seek prompt medical care if these occur.

5.5 Serious Adverse Events in Patients with Anemia Due to Chronic Kidney Disease and Not on Dialysis

The safety of JESDUVROQ has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting [see *Indications and Usage (1)*].

In a large cardiovascular outcomes trial in adults with anemia of CKD who were not on dialysis (ASCEND-ND), an increased risk of cardiovascular mortality, stroke, thromboembolism, serious acute kidney injury, hospitalization for heart failure, and serious gastrointestinal erosions was observed in patients treated with JESDUVROQ compared to rhEPO.

5.6 Malignancy

Because increased hypoxia inducible factor (HIF)-1 levels may be associated with unfavorable effects on cancer growth, JESDUVROQ has not been studied and is not recommended in patients with active malignancies. Malignancies were observed in 4.4% (1.9 per 100 PY) of patients treated with JESDUVROQ and 5.2% (2.3 per 100 PY) of patients treated with rhEPO. No evidence of increased carcinogenicity was observed in animal studies [see *Nonclinical Toxicology (13.1)*].

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Increased Risk of Death, Myocardial Infarction, Stroke, Venous Thromboembolism, and Thrombosis of Vascular Access [see *Boxed Warning, Warnings and Precautions (5.1)*].
- Risk of Hospitalization for Heart Failure [see *Warnings and Precautions (5.2)*].
- Hypertension [see *Warnings and Precautions (5.3)*].
- Gastrointestinal Erosion [see *Warnings and Precautions (5.4)*].

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of JESDUVROQ was evaluated in adults with dialysis-dependent chronic kidney disease with anemia in the ASCEND-D trial based on an on-study analysis (on and off treatment) [see *Clinical Studies (14.1)*]. Patients were randomized to JESDUVROQ or rhEPO (epoetin alfa for patients on hemodialysis; darbepoetin alfa for patients on peritoneal dialysis). Of the 2,964 patients randomized in the trial, 1,487 were randomized to JESDUVROQ, 1,316 (88.5%) of whom were on hemodialysis and 171 (11.5%) of whom were on peritoneal dialysis.

The median extent of exposure to JESDUVROQ and rhEPO was similar. In the JESDUVROQ treatment arm, 65% of the participants were exposed to at least 18 months of JESDUVROQ and 29% of participants received JESDUVROQ for at least 2.5 years.

JESDUVROQ was non-inferior to rhEPO on the time to first occurrence of major adverse cardiovascular events (MACE) in adults with anemia due to CKD who were on dialysis [see *Clinical Studies (14.1)*].

Permanent treatment discontinuation due to an adverse reaction was reported in 19% of patients treated with JESDUVROQ and 18% of patients treated with rhEPO. No specific adverse reaction resulted in permanent treatment discontinuation in >1% of patients treated with JESDUVROQ.

The most common adverse reactions ($\geq 10\%$ of JESDUVROQ-treated patients) were hypertension, thrombotic vascular events, and abdominal pain.

Table 4 lists the most common adverse reactions (reported in $\geq 5\%$ of patients treated with JESDUVROQ).

Table 4: Adverse Reactions Reported in ≥5% of Patients Treated with JESDUVROQ in the ASCEND-D Trial

Adverse Reaction	JESDUVROQ (n = 1,482) %	rhEPO (n = 1,474) %
Hypertension	24	24
Abdominal pain ^a	11	8
Dizziness	7	6
Hypersensitivity ^b	7	7

rhEPO = Recombinant human erythropoietin.

^a Includes unspecified abdominal pain, upper abdominal pain, abdominal discomfort.

^b Includes rash, urticaria and dermatitis.

Thrombotic Vascular Events

Adjudicated thrombotic vascular events (fatal and non-fatal) were observed in 9.8 per 100 PY of patients receiving JESDUVROQ and in 11.7 per 100 PY of patients receiving rhEPO (see Table 5).

Table 5: Adjudicated Thrombotic Vascular Events (Fatal and Non-Fatal) in the ASCENDD Trial^a

Event	JESDUVROQ (n = 1,482)	rhEPO (n = 1,474)
	Rate per 100 PY	Rate per 100 PY
Vascular access thrombosis	5.0	6.3
Myocardial infarction	3.4	4.1
Stroke	1.2	1.5
Deep vein thrombosis	0.7	0.6
Pulmonary embolism	0.3	0.4

PY = Person Years; rhEPO = Recombinant human erythropoietin.

^a These data are not an adequate basis for comparison of rates between the study drug and the active control.

7 DRUG INTERACTIONS

7.1 CYP2C8 Inhibitors

Concomitant administration of strong CYP2C8 inhibitors (e.g., gemfibrozil) with JESDUVROQ is contraindicated due to a marked increase in daprodustat exposure [see *Contraindications (4), Clinical Pharmacology (12.3)*]. Concomitant administration of moderate CYP2C8 inhibitors (e.g., clopidogrel) increases daprodustat exposure [see *Clinical Pharmacology (12.3)*]. Reduce the starting dose of JESDUVROQ by half when initiating treatment in patients on clopidogrel or a moderate CYP2C8 inhibitor except in

patients whose starting dose is already 1 mg. Monitor hemoglobin and adjust the dose of JESDUVROQ when initiating or stopping therapy with clopidogrel or a moderate CYP2C8 inhibitor during treatment with JESDUVROQ [see *Dosage and Administration* (2.6)].

7.2 CYP2C8 Inducers

CYP2C8 inducers (e.g., rifampin) may decrease daprodustat exposure, which may result in loss of efficacy. Monitor hemoglobin and adjust the dose of JESDUVROQ when initiating or stopping therapy with CYP2C8 inducers during treatment with JESDUVROQ [see *Clinical Pharmacology* (12.3)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data with JESDUVROQ use in pregnant women are insufficient to establish a drug associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are risks to the mother and the fetus associated with CKD (see *Clinical Considerations*). Daprodustat administered orally to pregnant rats and rabbits during the period of organogenesis was associated with adverse fetal outcomes, including embryonic and fetal loss and reduced fetal weight, at doses that caused maternal toxicity and polycythemia (see *Data*). Advise pregnant women of the potential risk to the fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk: CKD in pregnancy increases the risk for maternal hypertension, preeclampsia, miscarriage, stillbirth, preterm delivery, low birth weight infants, and polyhydramnios.

Data

Animal Data: Daprodustat was orally administered to pregnant rats at 0.5, 7, or 60 mg/kg/day from gestation day 6 to gestation day 17 during the period of organogenesis. No adverse effects were observed at doses less than or equal to 7 mg/kg/day (3 times the maximum recommended human dose [MRHD] based on body surface area). Daprodustat administration resulted in post-implantation loss, increased embryofetal death, and reduction in skeletal ossification in rats at a dose of 60 mg/kg/day (24 times the MRHD based on body surface area), which was associated with maternal toxicity (reduced body weight gain or weight loss). Maternal toxicity occurred at doses associated with polycythemia.

Daprodustat was orally administered to pregnant rabbits at doses of 4, 30, or 60 mg/kg/day from gestation day 7 until gestation day 19 during the period of

organogenesis. No adverse effects were observed at doses less than or equal to 30 mg/kg/day (24 times the MRHD based on body surface area). Daprodustat administration was associated with a low incidence of abortions and fetal skeletal malformations (irregularly shaped anterior fontanelle, manubrium, fused sternal centra, and microphthalmia) at a dose of 60 mg/kg/day (49 times the MRHD based on body surface area) in the presence of maternal toxicity (reduced body weight gain or weight loss) and polycythemia.

In a pre- and postnatal development study, pregnant rats were dosed orally with daprodustat from implantation until weaning (gestation day 6 to lactation day 21) at 0.8, 7, or 40 mg/kg/day concomitantly with 3 major human metabolites of daprodustat. No adverse effects were observed at doses less than or equal to 7 mg/kg/day (3 times the MRHD based on body surface area). Maternal toxicity (in the presence of polycythemia) was noted at 40 mg/kg/day (16 times the MRHD based on body surface area), which was associated with increased pup deaths and decreased pup weights.

8.2 Lactation

Risk Summary

There are no data on the presence of daprodustat in human milk, the effects on the breastfed child, or the effects on milk production. Daprodustat is present in the milk of lactating rats (*see Data*). When a drug is present in animal milk, it is likely that the drug will be present in human milk. Given the serious adverse reactions seen in adults treated with JESDUVROQ, such as thrombotic vascular events, advise patients not to breastfeed during treatment with JESDUVROQ, and for one week after the final dose.

Data

In a pre- and postnatal development study in rats, when daprodustat was orally administered to maternal rats during the lactation period, the drug was detected in plasma of suckling pups on postnatal day 10. The plasma concentration of daprodustat in pups was 2.3% to 3.7% of daprodustat detected in the plasma of dams when dosed at 40 mg/kg/day.

8.4 Pediatric Use

Safety and effectiveness of JESDUVROQ in pediatric patients have not been established.

8.5 Geriatric Use

Of the total number of subjects treated with JESDUVROQ in the ASCEND-D study (n = 2,964), 480 (32%) subjects were aged 65 years and older, and 159 (11%) were aged 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. No other reported clinical experience has identified differences in responses between the elderly and younger patients.

8.6 Hepatic Impairment

No adjustment of the starting dose is required in patients with mild hepatic impairment (Child-Pugh Class A).

Reduce the starting dose of JESDUVROQ by half in patients with moderate hepatic impairment (Child-Pugh Class B) except in patients whose starting dose is already 1 mg

[see *Clinical Pharmacology (12.3)*].

JESDUVROQ has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, JESDUVROQ is not recommended in patients with severe hepatic impairment.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

JESDUVROQ contains daprodustat, which is not a controlled substance.

9.2 Abuse

Drug abuse is intentional non-therapeutic use of a drug, even once, for its rewarding psychological or physiological effects. Abuse of JESDUVROQ may be seen in athletes for the effects on erythropoiesis.

Abuse-Related Adverse Reactions

There are no data on the abuse of JESDUVROQ in humans. Daprodustat and its metabolites neither selectively penetrate the central nervous system, nor produce behavioral effects in animals that are consistent with central nervous system activity.

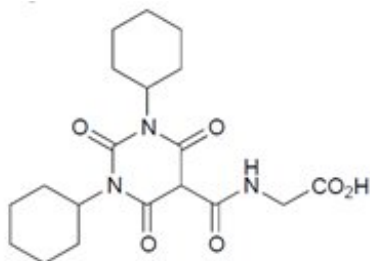
Misuse of drugs that increase erythropoiesis, such as JESDUVROQ, by healthy persons may lead to polycythemia, which may be associated with life-threatening cardiovascular complications (e.g., stroke, myocardial infarction, and thromboembolism).

10 OVERDOSAGE

Headache and gastrointestinal adverse reactions (e.g., nausea) may be seen with acute overdose with JESDUVROQ. There is no specific antidote. Hemodialysis will not substantially remove daprodustat because it is highly protein bound.

11 DESCRIPTION

JESDUVROQ contains daprodustat, an inhibitor of hypoxia inducible factor (HIF), prolyl 4-hydroxylases (PH)1, PH2 and PH3. The chemical name of daprodustat is N-[(1,3-dicyclohexylhexahydro-2,4,6-trioxopyrimidin-5-yl) carbonyl]glycine. The molecular formula of daprodustat is C₁₉H₂₇N₃O₆, and its molecular mass is 393.43. The structural formula is shown below.



Daprodustat is a white to off-white powder that is poorly soluble in water.

Each JESDUVROQ oral tablet contains 1 mg, 2 mg, 4 mg, 6 mg, or 8 mg of daprodustat. Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, mannitol and microcrystalline cellulose. The tablet film-coating inactive ingredients include hypromellose, iron oxide black (1 mg, 2 mg, and 6 mg tablets), iron oxide red and iron oxide yellow (1 mg, 2 mg, 6 mg, and 8 mg tablets), polyethylene glycol, and titanium dioxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Daprodustat is a reversible inhibitor of HIF-PH1, PH2 and PH3 (IC₅₀ in the low nM range). This activity results in the stabilization and nuclear accumulation of HIF-1 α and HIF-2 α transcription factors, leading to increased transcription of the HIF-responsive genes, including erythropoietin.

12.2 Pharmacodynamics

Effects on Erythropoiesis

Daprodustat increases endogenous erythropoietin in a dose-dependent manner within 6 to 8 hours after administration. With repeat doses, peak increases in reticulocyte counts occur between 7 and 15 days, with subsequent increases in red blood cell production. New hemoglobin steady-state levels are reached several weeks (approximately 4 weeks in ESA-users and approximately 16-20 weeks in ESA-non-users) after initial administration.

Effects on Iron Metabolism and Utilization

Daprodustat increased serum transferrin and total iron binding capacity (TIBC) and decreased serum ferritin, transferrin saturation, and hepcidin when administered for 52 weeks in adults on dialysis with anemia due to CKD.

Cardiac Electrophysiology

At a dose 10 times the maximum recommended dose, daprodustat does not prolong the QTc interval to any clinically relevant extent.

12.3 Pharmacokinetics

Daprodustat exposure generally increases in a dose-proportional manner over the range of approved doses. Steady-state concentrations are achieved within 24-hours of dosing.

Absorption

Following oral administration, daprodustat is readily absorbed with median time to peak concentration (T_{max}) in healthy subjects ranging from 1 hour to 4 hours. The absolute bioavailability of daprodustat is 65%. Administration of JESDUVROQ with a high fat/high calorie meal did not significantly alter daprodustat exposure compared to administration in the fasted state.

Distribution

Daprodustat has an approximately equal distribution between plasma and blood cells (blood:plasma ratio of 1.23). Following intravenous dosing, the volume of distribution at steady-state in healthy subjects is 14.3 L. In vitro, plasma protein binding of daprodustat is >99%.

Elimination

The terminal elimination half-life of daprodustat is approximately 1 hour to 4 hours.

Metabolism: In vitro, daprodustat is primarily metabolized by CYP2C8 (95% contribution), with a minor contribution by CYP3A4 (5%).

Following oral or intravenous administration of radiolabeled daprodustat to healthy adults, approximately 40% of the total circulating radioactivity in plasma was daprodustat, and the remaining 60% was metabolites.

In patients treated with JESDUVROQ, the parent drug is the principal circulating component in plasma. Three metabolites, each accounting for more than 10% of circulating drug-related material, have been identified; in vitro and non-clinical data suggest that each may contribute to the pharmacologic response in vivo; however, the extent of this contribution is unknown.

Excretion: Mean clearance from plasma was 18.9 L/h, which correlates to blood clearance of 15 L/h and equates to a hepatic extraction of approximately 18%.

Within seven days of an oral dose of radiolabeled daprodustat, 74% of the radioactivity was recovered in the feces, and 21% in the urine. Approximately 99.5% of the dose was excreted as oxidative metabolites, with the rest accounted for by daprodustat.

Specific Populations

Elderly: Population pharmacokinetic analyses in adults with CKD (22 years to 93 years) showed that age did not influence the pharmacokinetics of daprodustat.

Renal Impairment: The steady-state exposure of daprodustat is similar in patients with normal renal function and those with varying degrees of renal impairment; daprodustat exposure is not significantly impacted by hemodialysis or peritoneal dialysis. The systemic exposure of daprodustat metabolites was higher in patients with Stage 3 to 5 CKD compared to those with normal renal function. Exposures of metabolites were higher on non-dialysis days compared to dialysis days.

Hepatic Impairment: Following administration of a single JESDUVROQ 6 mg dose, mean daprodustat C_{max} and AUC increased by 2-fold and unbound exposure increased by 2.3-fold in subjects with moderate hepatic impairment (Child-Pugh Class B) compared to subjects with normal hepatic and renal function. For those with mild hepatic impairment (Child-Pugh Class A), mean daprodustat C_{max} was similar while AUC increased by 1.5-fold and unbound C_{max} and AUC increased by 1.6 and 2.2-fold, respectively, compared to subjects with normal hepatic and renal function. The effect of severe hepatic impairment (Child-Pugh Class C) on the pharmacokinetics of daprodustat is unknown as there have been no studies of JESDUVROQ in patients with severe hepatic impairment.

Drug Interaction Studies

Clinical Studies: Effect of CYP2C8 Inhibitors on the Pharmacokinetics of Daprodustat: The concomitant administration of gemfibrozil 600 mg twice a day for 5 days (strong CYP2C8 inhibitor) with a single 100 mg dose of JESDUVROQ on Day 4 of gemfibrozil

administration resulted in an 18.6-fold increase in $AUC_{(0-\infty)}$ and a 3.9-fold increase in C_{max} of daprodustat [see *Contraindications (4)*].

The concomitant administration of trimethoprim 200 mg twice a day for 5 days (CYP2C8 weak inhibitor) and 25 mg single dose of JESDUVROQ on Day 4 of trimethoprim administration resulted in a 1.5-fold increase in $AUC_{(0-\infty)}$ and a 1.3-fold increase in C_{max} of daprodustat.

Daprodustat AUC and C_{max} are expected to increase at least 4-fold and 3-fold, respectively, following concomitant administration of daprodustat with clopidogrel 75 mg once daily (moderate CYP2C8 inhibitor).

Following 4 weeks of JESDUVROQ dosing, hemoglobin changes from baseline were similar in subjects with and without concomitant use of clopidogrel.

Effect of Daprodustat on the Pharmacokinetics of Other Drugs: Clinical drug interaction studies showed that daprodustat inhibition of CYP2C8 and OATP1B1/OATP1B3 demonstrated no clinically significant effect on pioglitazone (CYP2C8 substrate) or rosuvastatin (OATP1B1/OATP1B3 substrate) C_{max} or AUC.

In vitro studies: Some oxidative metabolites of daprodustat are substrates of Organic Anion Transporter (OAT)1 or OAT3; however, the clinical significance of this is unknown. Daprodustat is a substrate of Breast Cancer Resistance Protein (BCRP); however, the risk of significant drug interactions between daprodustat and BCRP inhibitors is considered low given the absorption and metabolism profile of daprodustat.

Daprodustat is not an inducer of CYP1A2, CYP2B6 and CYP3A4. Daprodustat is not an inhibitor of P-glycoprotein (P-gp) and BCRP.

Daprodustat is not a substrate of CYP1A2, CYP2B6, CYP2C9, CYP2C19, CYP2D6 and P-gp. The major metabolites are not substrates of OATP1B1, OATP1B3, OATP2B1, Organic Cation Transporter (OCT)1, OCT2, Multidrug and Toxin Extrusion (MATE)1 and MATE2-K. Daprodustat and its major metabolites are not inhibitors of CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2C19, CYP2D6, CYP3A4, OATP1B1, OATP1B3, OATP2B1, OCT1, OAT1, OAT3, OCT2, MATE1 and MATE2-K.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Daprodustat was not carcinogenic in two-year carcinogenicity studies when administered orally at doses of 0.02, 0.1, 0.8, or 4 mg/kg/day (males) / 7 mg/kg/day (females) in rats (up to 3 times the MRHD based on body surface area) and 0.2, 0.8, or 3 mg/kg/day (including subcutaneous injection of major human metabolites of daprodustat) in mice (approximating the MRHD based on body surface area).

Daprodustat was negative for mutagenic or clastogenic potential in the in vitro bacterial reverse mutation assay, the in vitro human lymphocyte chromosomal aberration assay, and the in vivo rat bone marrow micronucleus assay.

In a fertility and early embryonic development study in rats, daprodustat was administered orally at doses of 2, 7, or 100 mg/kg/day in females, resulting in maternal toxicity of reduced body weight gain and decreased mean uterine weight (in the presence of polycythemia), associated with decreased number of corpora lutea,

implantations, and live fetuses, and increased post-implantation loss at the dose of 100 mg/kg/day (41 times the MRHD based on body surface area).

14 CLINICAL STUDIES

14.1 Anemia Due to Chronic Kidney Disease in Adults on Dialysis

The efficacy and safety of JESDUVROQ were evaluated in 2,964 adults with anemia due to CKD on dialysis and receiving an ESA at the time of study entry in a randomized, sponsor-blind, active-controlled, global, multicenter, event-driven clinical trial (ASCEND-D; NCT02879305). Patients were stratified by dialysis type and were required to be on dialysis for at least 4 months prior to the first dose of JESDUVROQ. Patients on hemodialysis (HD) were randomized 1:1 to receive oral JESDUVROQ (n = 1,316) or intravenous epoetin alfa (n = 1,308) while patients on peritoneal dialysis (PD) were randomized 1:1 to receive oral JESDUVROQ (n = 171) or subcutaneous darbepoetin alfa (n = 169).

Key exclusion criteria included: ferritin ≤ 100 ng/ml (≤ 100 mcg/L), transferrin saturation $\leq 20\%$ at screening; evidence of non-renal anemia; cardiovascular abnormalities (including myocardial infarction, acute coronary syndrome, stroke or transient ischemic attack within 4 weeks of screening, New York Heart Association (NYHA) Class IV heart failure, and uncontrolled hypertension); liver disease; history of malignancy within 2 years of screening; current treatment of cancer and complex kidney cyst.

Dosing in each treatment arm followed a protocol-specified adjustment algorithm to achieve and/or maintain a hemoglobin target of 10 to 11 g/dL. The starting dose of JESDUVROQ was 4 mg, 6 mg, 8 mg, or 12 mg orally once daily, based on prior ESA dose. The starting dose of either epoetin alfa (HD patients) or darbepoetin alfa (PD patients) was the same as the patient's current dose rounded to the nearest study dose. Patients receiving other ESAs were switched to the epoetin alfa or darbepoetin alfa equivalent starting dose. The median doses at Week 52 were 6 mg per day for JESDUVROQ, 8,000 units per week for epoetin alfa, and 150 mcg every four weeks for darbepoetin alfa. Most patients (86%) were exposed to randomized treatment for greater than 6 months (median 26 months for JESDUVROQ and 26 months for rhEPO). The median number of dose adjustments from Day 1 to Week 28 was 2 (interquartile range: 1 to 3) for JESDUVROQ and 2 (interquartile range: 1 to 3) for rhEPO. The median number of dose adjustments from Week 28 to Week 52 was 1 (interquartile range: 1 to 2) for JESDUVROQ and 2 (interquartile range: 1 to 3) for rhEPO.

The mean age of the patients in this study was 57 years (range 18-95), 57% were males, 67% were Caucasian, 16% were Black, and 12% were Asian. In the US region, 39% of patients were Black. Approximately 25% of the population was Hispanic or Latino. The largest regions of enrollment were the US (29%) and Eastern Europe/South Africa (28%). Common comorbid conditions included hypertension (92%), hyperlipidemia (50%) and diabetes mellitus (42%).

Effects on Hemoglobin

The efficacy and safety of JESDUVROQ were evaluated as co-primary endpoints: the mean change in hemoglobin from baseline to the Evaluation Period (Weeks 28 to 52) and time to first adjudicated MACE (defined as all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke), using a non-inferiority comparison to rhEPO (epoetin alfa

and darbepoetin alfa) for both endpoints.

The lower limit of the 95% confidence interval (CI) for the overall hemoglobin treatment difference was greater than the pre-specified non-inferiority margin of -0.75 g/dL, demonstrating non-inferiority of JESDUVROQ to rhEPO with respect to the mean change in hemoglobin between baseline and over the Evaluation Period (see Table 6). Results were similar in patients receiving either hemodialysis or peritoneal dialysis.

Table 6: Change in Hemoglobin in Adults with Anemia Due to Chronic Kidney Disease Receiving Dialysis: ASCEND-D Trial (ITT Analysis)^a

Assessment	JESDUVROQ (n = 1,487)	rhEPO^b (n = 1,477)
Primary endpoint: change in Hgb^c		
Mean baseline Hgb, g/dL (SD)	10.4 (1.0)	10.4 (1.0)
Hgb change, g/dL (SE) ^{d,e}	0.3 (0.02)	0.1 (0.02)
Mean treatment difference (95% CI) ^e	0.2 (0.1, 0.2)	
Change in Hgb - hemodialysis patients^f		
Number of patients	1,316	1,308
Mean baseline Hgb, g/dL (SD)	10.4 (1.0)	10.4 (1.0)
Hgb change, g/dL (SE) ^{d,e}	0.3 (0.02)	0.1 (0.02)
Mean treatment difference (95% CI) ^e	0.2 (0.1, 0.3)	
Change in Hgb - peritoneal dialysis patients^f		
Number of patients	171	169
Mean baseline Hgb, g/dL (SD)	10.3 (1.0)	10.2 (1.0)
Hgb change, g/dL (SE) ^{d,e}	0.4 (0.1)	0.2 (0.1)
Mean treatment difference (95% CI) ^e	0.2 (-0.04, 0.3)	

CI = Confidence interval; Hgb = Hemoglobin; ITT = Intent to treat;
rhEPO = Recombinant human erythropoietin; SD = Standard deviation; SE = Standard

error.

^a Intent to Treat (ITT) analyses included observed and imputed values on and off treatment after randomization. Eight percent of patients had no observed hemoglobin during Weeks 28 to 52.

^b Hemodialysis patients received epoetin alfa and peritoneal dialysis patients received darbepoetin alfa.

^c Adjusted for multiplicity.

^d Mean Hgb change from baseline to Evaluation Period (EP): Weeks 28 to 52.

^e Adjusted for baseline covariates.

^f Not adjusted for multiplicity.

Cardiovascular Outcomes

The hazard ratio for the time to first occurrence of MACE, a composite of all-cause mortality, non-fatal myocardial infarction, and non-fatal stroke, comparing JESDUVROQ to rhEPO was 0.93 (95% CI 0.81, 1.07) (Table 7). Non-inferiority of JESDUVROQ to rhEPO on MACE was achieved because the upper limit of the 95% CI for the MACE hazard ratio was less than the pre-specified non-inferiority margin of 1.25.

Table 7: Major Adverse Cardiovascular Events in the ASCEND-D Trial (ITT Analysis)^a

Co-primary composite endpoint	JESDUVROQ (n = 1,487)	rhEPO^b (n = 1,477)
First occurrence of MACE ^c , n	374	394
All-cause mortality ^d , n	244	233
Non-fatal myocardial infarction ^d , n	101	126
Non-fatal stroke ^d , n	29	35
Hazard ratio (95% CI) ^e	0.93 (0.81, 1.07)	
Incidence rate per 100 PY	11.1	11.9

CI = Confidence interval; ITT = Intent to treat; MACE = Major adverse cardiovascular events; PY = Person Years; rhEPO = Recombinant human erythropoietin.

^a ITT analyses included events on and off treatment after randomization.

^b Hemodialysis patients received epoetin alfa; peritoneal dialysis patients received darbepoetin alfa.

^c Co-primary endpoint.

^d Component of composite endpoint.

^e Adjusted for baseline covariates.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

JESDUVROQ tablets contain 1 mg, 2 mg, 4 mg, 6 mg or 8 mg of daprodustat.

Tablet Strength	Package Configuration and NDC Number	Tablet Description and Markings
1 mg	30 count bottle (NDC 0173-0897-13)	Round, gray, biconvex, film-coated tablets debossed with "GS KF" on one side
	100 count blister pack (NDC 0173-0897-56)	
2 mg	30 count bottle (NDC 0173-0903-13)	Round, yellow, biconvex, film-coated tablets debossed with "GS V7" on one side
	100 count blister pack (NDC 0173-0903-56)	
4 mg	30 count bottle (NDC 0173-0906-13)	Round, white, biconvex, film-coated tablets debossed with "GS 13" on one side
	100 count blister pack (NDC 0173-0906-56)	
6 mg	30 count bottle (NDC 0173-0911-13)	Round, pink, biconvex, film-coated tablets debossed with "GS IM" on one side
	100 count blister pack (NDC 0173-0911-56)	
8 mg	30 count bottle (NDC 0173-0914-13)	Round, orange, biconvex, film-coated tablets debossed with "GS 5E" on one side
	100 count blister pack (NDC 0173-0914-56)	

Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Inform patients:

- Of the increased risks of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access [see *Warnings and Precautions (5.1)*].
- Of the risk of hospitalization due to heart failure, the symptoms and signs of heart failure and to promptly report these symptoms to their healthcare provider [see *Warnings and Precautions (5.2)*].
- Of the risk of hypertension, to undergo regular blood pressure monitoring and to adhere to the prescribed anti-hypertensive regimen [see *Warnings and Precautions*].

(5.3)].

- Of the risk of gastric erosions and gastrointestinal bleeding, the associated symptoms and signs and to report these symptoms to their healthcare provider [see *Warnings and Precautions (5.4)*].
- Of the need to have regular laboratory tests for hemoglobin [see *Dosage and Administration (2.1, 2.4)*].
- Of the need to inform their healthcare provider if they are taking strong CYP2C8 inhibitors, including gemfibrozil or moderate CYP2C8 inhibitors [see *Contraindications (4), Drug Interactions (7.1)*].
- Pregnancy
JESDUVROQ may cause fetal harm. Advise females to inform their healthcare provider of a known or suspected pregnancy [see *Use in Specific Populations (8.1)*].
- Lactation
Advise females not to breastfeed during treatment with JESDUVROQ and for one week after the final dose [see *Use in Specific Populations (8.2)*].

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Manufactured by

GlaxoSmithKline

Durham, NC 27701

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JDV:3PI

PHARMACIST - DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

MEDICATION GUIDE
JESDUVROQ (jez-DOOV-rok)
(daprodustat)
tablets

What is the most important information I should know about JESDUVROQ?
JESDUVROQ may cause serious side effects, including:

- **Increased risk of death, heart attack, stroke, and blood clots.** These risks may happen if you are treated with JESDUVROQ to increase red blood cells (RBCs) to near the same level found in healthy people. These risks may be increased if you have heart or blood vessel problems, or problems with blood flow to your brain (cerebrovascular disease). Blood clots can form in the blood vessels (veins), including in your legs (deep vein thrombosis or DVT), lungs (pulmonary embolism or PE), and in your dialysis access (vascular access thrombosis or VAT).
Get medical help right away if you get any of the following symptoms:

chest pain

sudden trouble seeing

trouble breathing or shortness of breath

sudden trouble walking, dizziness, loss of balance or coordination

pain in your leg or arm, with or without swelling

lightheadedness or fainting

unusual coolness or warmth in arm or leg

dialysis access stops working

sudden confusion, trouble speaking, or trouble understanding others' speech

do not feel a vibration ("thrill") over the dialysis access area

sudden numbness or weakness in your face, arm, or leg, especially on one side of your body

See "What are the possible side effects of JESDUVROQ?" for more information about side effects.

If you decide to take JESDUVROQ, your healthcare provider should prescribe the lowest dose of JESDUVROQ that is necessary to reduce your chance of needing red blood cell transfusions.

What is JESDUVROQ?

JESDUVROQ is a prescription medicine used to treat anemia that is caused by chronic kidney disease (CKD) in adults who have been on dialysis for at least 4 months. People with anemia have a lower-than-normal number of RBCs. JESDUVROQ works by increasing a protein called erythropoietin to help your body make more RBCs.

JESDUVROQ is used to reduce or avoid the need for RBC transfusions.

If your hemoglobin level stays too high or if your hemoglobin goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen if you take JESDUVROQ, even if you do not have an increase in your hemoglobin levels.

JESDUVROQ has not been proven to improve quality of life, tiredness (fatigue), or well-being.

JESDUVROQ should not be used:

- in place of emergency treatment for anemia (red blood cell transfusions).
- for the treatment of anemia that is caused by CKD in people who are not on dialysis. It is not known if JESDUVROQ is safe and effective in children.

Do not take JESDUVROQ if you:

- take certain medicines called strong CYP2C8 inhibitors such as gemfibrozil. Ask your healthcare provider if you are not sure.

- have high blood pressure that is not controlled (uncontrolled hypertension)

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

- have heart disease
- have had a stroke
- have a history of heart failure
- have high blood pressure
- have a history of damage to the lining of the stomach, the tube that connects the mouth and stomach (esophagus), or intestines
- have a history of stomach ulcers (peptic ulcer disease)
- smoke tobacco or drink alcohol
- have cancer
- have liver problems
- are pregnant or plan to become pregnant. JESDUVROQ may cause harm to your unborn baby. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with JESDUVROQ.
- are breastfeeding or plan to breastfeed. It is not known if JESDUVROQ passes into your breast milk. Do not breastfeed during treatment with JESDUVROQ and for 1 week after your final dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking JESDUVROQ with certain other medicines may affect the way JESDUVROQ works.

How should I take JESDUVROQ?

- Take JESDUVROQ exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop JESDUVROQ without talking to your healthcare provider.
- Take your prescribed dose of JESDUVROQ 1 time a day.
- Swallow JESDUVROQ tablets whole. Do not cut, crush, or chew the tablet.
- JESDUVROQ can be taken with or without food.
- JESDUVROQ can be taken at the same time as iron supplements or medicines that control the amount of phosphorus in your blood (phosphate binders), if necessary.
- If you miss a dose of JESDUVROQ, take it as soon as you remember. If it is the same day as your next dose, skip the missed dose and take your next dose at your usual time. Do not take 2 doses at the same time to make up for the missed dose.
- If you take more than your prescribed dose of JESDUVROQ, contact your healthcare provider or go to the nearest hospital emergency room right away.
- Your healthcare provider will do certain blood tests before you start JESDUVROQ and during treatment as needed. Your healthcare provider may change your dose of JESDUVROQ based on the results of your blood tests.

What are the possible side effects of JESDUVROQ?

JESDUVROQ may cause serious side effects, including:

- **See “What is the most important information I should know about JESDUVROQ?”**
- **Risk of hospitalization for heart failure.** People who have a history of heart

failure have an increased risk of hospitalization for heart failure with JESDUVROQ. Tell your healthcare provider right away if you get worsening signs and symptoms of heart failure, including:

shortness of breath or trouble breathing

sudden weight gain

swelling of your feet, ankles or legs

feeling tired or weak

- **High blood pressure.** High blood pressure is common with JESDUVROQ. Your blood pressure may go up or worsen, and may be difficult to treat during treatment with JESDUVROQ. Your healthcare provider should check your blood pressure regularly during treatment with JESDUVROQ. If your blood pressure increases, your healthcare provider may prescribe a new medicine or may change the dose of your current blood pressure medicine.
- **Damage to the lining of the stomach, the tube that connects the mouth and stomach (esophagus), and intestines (gastrointestinal erosion).** Your risk of gastrointestinal erosion may increase if you have a history of gastrointestinal erosion, stomach ulcers (peptic ulcer disease), use certain medicines that increase the risk of gastrointestinal erosion, or currently smoke tobacco or drink alcohol. Some people who have bleeding in the stomach and intestines may need to receive transfusions. Tell your healthcare provider if you have any of these symptoms:

stomach-area (abdominal) discomfort or pain

black, tarry stools

nausea or vomiting

trouble swallowing

blood in your vomit or stool

pain in your throat or chest

- **Cancer.** Cancers have happened in people treated with JESDUVROQ. Talk to your healthcare provider if you have any concerns about cancer.

The most common side effects of JESDUVROQ include:

- high blood pressure. See “**High blood pressure**” above.
- heart attack, stroke, and blood clots in the dialysis access, legs, or lungs. See “**What is the most important information I should know about JESDUVROQ?**” above.
- stomach area (abdominal) pain.

These are not all the possible side effects of JESDUVROQ.

Call your doctor for medical advice about side effects. You may report side effects

to FDA at 1-800-FDA-1088.

How should I store JESDUVROQ?

- Store JESDUVROQ at room temperature between 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of JESDUVROQ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use JESDUVROQ for a condition for which it was not prescribed. Do not give JESDUVROQ 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 JESDUVROQ that is written for health professionals.

What are the ingredients in JESDUVROQ?

Active Ingredient: daprodustat.

Inactive Ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, and microcrystalline cellulose.

Tablet film-coating: hypromellose, iron oxide black (1 mg, 2 mg, and 6 mg tablets), iron oxide red and iron oxide yellow (1 mg, 2 mg, 6 mg, and 8 mg tablets), polyethylene glycol, and titanium dioxide.

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Manufactured by

GlaxoSmithKline

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JDV:1MG

For more information, go to www.JESDUVROQ.com or call GlaxoSmithKline (GSK) at 1-888-825-5249.

This Medication Guide has been approved by the U.S. Food and Drug Administration
Issued: February 2023

PRINCIPAL DISPLAY PANEL

NDC 0173-0897-13

Jesduvroq

(daprodustat) tablets

1 mg

Rx only

GSK

Dispense the accompanying Medication Guide to each patient

30 tablets

Each tablet contains 1 mg of daprodustat.

Swallow tablets whole. Do not cut, crush or chew the tablet.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperatures].

Do not accept if safety seal under cap is broken or missing.

Recommended Dosage:

See Prescribing Information.

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Durham, NC 27701

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Rev. 3/23

A087261 (62000000087261)

NDC 0173-0897-13
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Do not accept if safety seal under cap is missing or broken.
Recommended Dosage:
See Prescribing Information.
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Rev. 3/23

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PRINCIPAL DISPLAY PANEL

NDC 0173-0903-13

Jesduvroq

(daprodustat) tablets

2 mg

Rx only

GSK

Dispense the accompanying Medication Guide to each patient

30 tablets

Each tablet contains 2 mg of daprodustat.

Swallow tablets whole. Do not cut, crush or chew the tablet.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperatures].

Do not accept if safety seal under cap is broken or missing.

Recommended Dosage:

See Prescribing Information.

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Rev. 3/23

A087262 (62000000087262)

NDC 0173-0903-13
Rx only

Jesduvroq
(daprodustat) tablets

2 mg

Dispense the accompanying Medication Guide to each patient

30 tablets

GSK

Each tablet contains 2 mg of daprodustat.
Swallow tablets whole. Do not cut, crush or chew the tablet.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperature].
Do not accept if safety seal under cap is missing or broken.
Recommended Dosage:
See Prescribing Information.
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Rev. 3/23

A087262

GTIN (01) XXXXXXXXXXXXXXXX
LOT (10) XXXXX
EXP MMM YYYY
SN (21) XXXXXXXXXXXXX

PRINCIPAL DISPLAY PANEL

NDC 0173-0906-13

Jesduvroq

(daprodustat) tablets

4 mg

Rx only

GSK

Dispense the accompanying Medication Guide to each patient

30 tablets

Each tablet contains 4 mg of daprodustat.

Swallow tablets whole. Do not cut, crush or chew the tablet.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperatures].

Do not accept if safety seal under cap is broken or missing.

Recommended Dosage:

See Prescribing Information.

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Rev. 3/23

A087263 (62000000087263)

NDC 0173-0906-13
Rx only

Jesduvroq
(daprodustat) tablets

4 mg

Dispense the accompanying Medication Guide to each patient

30 tablets

Each tablet contains 4 mg of daprodustat.
Swallow tablets whole. Do not cut, crush or chew the tablet.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperature].
Do not accept if safety seal under cap is missing or broken.
Recommended Dosage:
See Prescribing Information.
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A087263

GTIN (01) XXXXXXXXXXXXXXXX
LOT (10) XXXXX
EXP MMM YYYY
SN (21) XXXXXXXXXXXXX

PRINCIPAL DISPLAY PANEL

NDC 0173-0911-13

Jesduvroq

(daprodustat) tablets

6 mg

Rx only

GSK

Dispense the accompanying Medication Guide to each patient

30 tablets

Each tablet contains 6 mg of daprodustat.

Swallow tablets whole. Do not cut, crush or chew the tablet.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperatures].

Do not accept if safety seal under cap is broken or missing.

Recommended Dosage:

See Prescribing Information.

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Rev. 3/23

A087264 (62000000087264)

NDC 0173-0911-13
Rx only

Jesduvroq
(daprodustat) tablets

6 mg

Dispense the accompanying Medication Guide to each patient

30 tablets

GSK Each tablet contains 6 mg of daprodustat.
Swallow tablets whole. Do not cut, crush or chew the tablet.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperature].
Do not accept if safety seal under cap is missing or broken.
Recommended Dosage:
See Prescribing Information.
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Rev. 3/23

A087264

GTIN (01) XXXXXXXXXXXXXXXX
LOT (10) XXXXX
EXP MMMM YYYY
SN (21) XXXXXXXXXXXXX

PRINCIPAL DISPLAY PANEL

NDC 0173-0914-13

Jesduvroq

(daprodustat) tablets

8 mg

Rx only

GSK

Dispense the accompanying Medication Guide to each patient

30 tablets

Each tablet contains 8 mg of daprodustat.

Swallow tablets whole. Do not cut, crush or chew the tablet.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperatures].

Do not accept if safety seal under cap is broken or missing.

Recommended Dosage:

See Prescribing Information.

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Rev. 3/23

A087265 (62000000087265)

NDC 0173-0914-13
Rx only



Each tablet contains 8 mg of daprodustat.
Swallow tablets whole. Do not cut, crush or chew the tablet.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F to 86°F). [See USP Controlled Room Temperature].
Do not accept if safety seal under cap is missing or broken.
Recommended Dosage: See Prescribing Information.
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Rev. 3/23

Jesduvroq
(daprodustat) tablets

8 mg

Dispense the accompanying Medication Guide to each patient



30 tablets

3 0173-0914-13 2




A087265

GTIN (01) XXXXXXXXXXXXXXXX
LOT (10) XXXXX
EXP MMM YYYY
SN (21) XXXXXXXXXXXXX

JESDUVROQ

daprodustat tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0173-0897
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DAPRODUSTAT (UNII: JVR38ZM64B) (DAPRODUSTAT - UNII:JVR38ZM64B)	DAPRODUSTAT	1 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	GRAY	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	GS;KF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0897-13	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	01/31/2027
2	NDC:0173-0897-56	10 in 1 CARTON	02/01/2023	02/02/2023
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA216951	02/01/2023	01/31/2027

JESDUVROQ

daprodustat tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0173-0903
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DAPRODUSTAT (UNII: JVR38ZM64B) (DAPRODUSTAT - UNII:JVR38ZM64B)	DAPRODUSTAT	2 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	YELLOW	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	GS;V7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0903-13	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	04/30/2027
2	NDC:0173-0903-56	10 in 1 CARTON	02/01/2023	02/02/2023
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA216951	02/01/2023	04/30/2027

JESDUVROQ

daprodustat tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0173-0906
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DAPRODUSTAT (UNII: JVR38ZM64B) (DAPRODUSTAT - UNII:JVR38ZM64B)	DAPRODUSTAT	4 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	GS;13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0906-13	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	04/30/2027
2	NDC:0173-0906-56	10 in 1 CARTON	02/01/2023	02/02/2023
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA216951	02/01/2023	04/30/2027

JESDUVROQ

daprodustat tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0173-0911
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DAPRODUSTAT (UNII: JVR38ZM64B) (DAPRODUSTAT - UNII:JVR38ZM64B)	DAPRODUSTAT	6 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	GS;IM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0911-13	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	11/30/2026
2	NDC:0173-0911-56	10 in 1 CARTON	02/01/2023	02/02/2023
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA216951	02/01/2023	11/30/2026

JESDUVROQ

daprodustat tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0173-0914
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DAPRODUSTAT (UNII: JVR38ZM64B) (DAPRODUSTAT - UNII:JVR38ZM64B)	DAPRODUSTAT	8 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MANNITOL (UNII: 3OWL53L36A)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	GS;5E
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0914-13	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	11/30/2026
2	NDC:0173-0914-56	10 in 1 CARTON	02/01/2023	02/02/2023
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA216951	02/01/2023	11/30/2026

Labeler - GlaxoSmithKline LLC (167380711)

Revised: 8/2023

GlaxoSmithKline LLC