

Jesduvroq
(daprodustat) tablets
1 mg • 2 mg • 4 mg • 6 mg • 8 mg

Get to know **JESDUVROQ**

A novel treatment in a different class of medicine for Anemia of Chronic Kidney Disease (CKD) in adults on dialysis for at least 4 months

APPROVED USE

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.

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).
- in people who are not on dialysis.

IMPORTANT SAFETY INFORMATION

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).

Please see additional Important Safety Information throughout and accompanying Important Facts, including Serious Side Effects for JESDUVROQ.



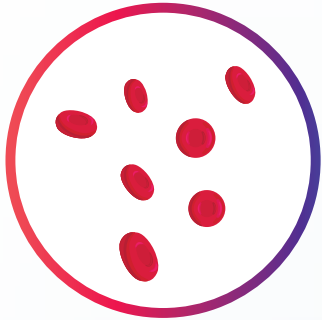
What is Anemia of CKD?

Anemia is a common complication of CKD that gets worse as kidney disease progresses.

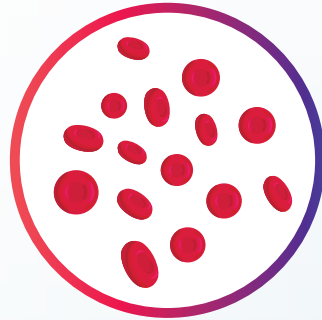
Anemia of CKD is a condition that occurs when you don't have enough red blood cells. Red blood cells contain a protein called hemoglobin (Hgb), which carries oxygen from your lungs to the rest of your body.

Red blood cells for people

With Anemia of CKD



Without Anemia of CKD



For illustrative purposes only; red blood cells will vary by individual.



Talk to your doctor.

You may have questions that your healthcare team can help answer. It's important to talk to your doctor about treatment if you are experiencing symptoms of Anemia of CKD.

Impact of Anemia of CKD

When your Hgb levels are low, your body must work with less oxygen, which can put a strain on vital organs like your heart and brain.

What causes it?



Anemia of CKD can be caused by many factors. One common cause occurs when your kidneys produce less erythropoietin (EPO), a hormone that tells your body to make red blood cells. Low levels of EPO decrease red blood cell production and can lead to anemia.

Why is it important to treat it?



Treating Anemia of CKD can help your body make more red blood cells. It also can help reduce the need for blood transfusions. This is important because getting blood transfusions may decrease your chances of qualifying for a kidney transplant.



JESDUVROQ has been clinically studied with a diverse population of patients on dialysis

JESDUVROQ was studied in a large clinical trial, including nearly 3,000 adults already receiving hemodialysis or peritoneal dialysis.

JESDUVROQ was studied in Anemia of CKD patients with a variety of other medical conditions such as diabetes or controlled hypertension (high blood pressure).

The patient population was diverse and included a variety of ages and different groups:

- 57% male and 43% female
- Average age was 57 years
- 67% Caucasian, 16% Black, 12% Asian
- 89% hemodialysis and 11% peritoneal dialysis

The trial assessed the efficacy and safety of JESDUVROQ.



JESDUVROQ was compared to the current standard of care ESA* to understand the change in Hgb during the evaluation period of Weeks 28 to 52 and incidence of serious cardiovascular events.

Patients in both treatment groups were dosed to achieve and/or maintain target Hgb levels of 10-11 g/dL.

**Compared to epoetin alfa or darbepoetin alfa, depending on type of dialysis.*

IMPORTANT SAFETY INFORMATION (cont.)

JESDUVROQ may cause other serious side effects, including: (cont.)

Get medical help right away if you get any of the following symptoms:

chest pain; trouble breathing or shortness of breath; pain in your leg or arm, with or without swelling; unusual coolness or warmth in arm or leg; sudden confusion, trouble speaking, or trouble understanding others' speech; sudden numbness or weakness in your face, arm, or leg, especially on one side of your body; sudden trouble seeing; sudden trouble walking, dizziness, loss of balance or coordination; lightheadedness or fainting; dialysis access stops working; do not feel a vibration ("thrill") over the dialysis access area.

JESDUVROQ can change your Hgb level— with a convenient pill

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JESDUVROQ offers similar changes to Hgb as the current standard of care and does it with a once-daily pill.



JESDUVROQ was as effective as an ESA, a current injectable treatment, in changing Hgb levels. Based on the clinical study, JESDUVROQ was comparable to the current standard of care in raising and maintaining Hgb levels.

Your results may vary.

Once-daily JESDUVROQ may allow for a flexible treatment schedule.

JESDUVROQ is taken once daily on your schedule, as prescribed by your doctor.

- You do not need to take it with a meal, so you are able to find a time that may work better for you or pair with a daily habit— like brushing your teeth.
- You can also take it with iron supplements or phosphate binders, if necessary.



Pill not representative of actual size or color.

IMPORTANT SAFETY INFORMATION (cont.)

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

If your hemoglobin level stays too high or 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.

Please see additional Important Safety Information throughout and accompanying Important Facts, including Serious Side Effects for JESDUVROQ.

JESDUVROQ is a different needle-free option to help treat and manage your Anemia of CKD

The following are questions you may have about JESDUVROQ. It is always important to consult with your healthcare team about your treatment plan.

How many patients' Hgb responded to treatment with JESDUVROQ?

73% of patients using JESDUVROQ responded and maintained their Hgb levels within the analysis range[†] during the evaluation period.

Based on the limits of the analysis, the results are descriptive. Your results may vary.

[†]Patients were dosed to achieve or maintain target Hgb levels of 10-11 g/dL. Analysis range (10-11.5 g/dL) is an extension of the target range to allow for variability.



IMPORTANT SAFETY INFORMATION (cont.)

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, esophagus, or intestines; have a history of stomach ulcers (peptic ulcer disease); smoke tobacco or drink alcohol; have cancer; have liver problems.

Does it matter how fast Hgb levels increase?



Yes, if your Hgb goes up too quickly, it could lead to serious health problems. **4% of patients** taking JESDUVROQ saw a rapid increase during the first 4 weeks of the study.[†]

Based on the limits of the analysis, the results are descriptive. Your results may vary.

[†]Rapid increase is defined as an increase of more than 2 g/dL during a 4-week period.

Will blood transfusions be needed?



While sometimes necessary to treat Anemia of CKD, getting a blood transfusion might reduce your chances of qualifying for a kidney transplant.

When taking JESDUVROQ, you may be able to reduce or avoid the need for blood transfusions. In the study, approximately **16% of patients** on JESDUVROQ needed a blood transfusion.

Based on the limits of the analysis, the results are descriptive. Your results may vary.

JESDUVROQ should not be used in place of emergency treatment for anemia.

IMPORTANT SAFETY INFORMATION (cont.)

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

- 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.

Please see additional Important Safety Information throughout and accompanying Important Facts, including Serious Side Effects for JESDUVROQ.

JESDUVROQ is the first in a novel class of treatment

JESDUVROQ will be prescribed by your doctor once daily



JESDUVROQ works differently.

JESDUVROQ helps your body make its own natural hormone, erythropoietin (EPO). How JESDUVROQ works is different from other currently available treatments—like erythropoiesis-stimulating agent (ESA) injections and iron supplements. The increase of EPO helps your body make more red blood cells, which contain Hgb.



JESDUVROQ is **not an injection** or infusion—it's a once-daily pill.

IMPORTANT SAFETY INFORMATION (cont.)

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.

JESDUVROQ may cause other serious side effects, including:

- **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; swelling of your feet, ankles, or legs; sudden weight gain; 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. If your blood pressure increases, your healthcare provider may prescribe a new medicine or may change the dose of your current blood pressure medicine.

Before starting JESDUVROQ, your doctor will work closely with you to:

- Identify any other reasons for your anemia.
- Test the amount of iron in your body and administer additional iron, if needed.
- Complete necessary blood tests to assess the health of your liver.
- Determine your starting dose of JESDUVROQ, which will depend on your Hgb level, or your ESA dose if you're on an ESA.

During treatment, your doctor will:

- Continue to monitor your Hgb to track changes in your levels.
- Adjust your dose of JESDUVROQ based on the results of your blood tests.

Once you've started taking JESDUVROQ:

- Continue to take JESDUVROQ exactly as your healthcare provider tells you to take it.
- 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.
- Do not change your dose or stop JESDUVROQ without talking to your healthcare provider.
- If you take more than your prescribed dose of JESDUVROQ, contact your healthcare provider or go to the nearest hospital emergency room right away.
- Schedule monitoring appointments with your doctor.
- Keep track of your Hgb levels. This will help you have a more informed conversation with your doctor.

Please see additional Important Safety Information throughout and accompanying Important Facts, including Serious Side Effects for JESDUVROQ.

Important information you should know about taking JESDUVROQ

While taking JESDUVROQ, side effects can occur. Talk with your doctor if you have any side effects that bother you or that do not go away.



In a clinical study, the cardiovascular safety of JESDUVROQ was compared to the current standard of care ESA, based on the first major adverse cardiovascular event (MACE), such as death, heart attack, or stroke. **Across those areas, JESDUVROQ had a similar incidence of serious cardiovascular events as an ESA.**

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
- trouble breathing or shortness of breath
- pain in your leg or arm, with or without swelling
- unusual coolness or warmth in arm or leg
- sudden confusion, trouble speaking, or trouble understanding others' speech
- sudden numbness or weakness in your face, arm, or leg, especially on one side of your body
- sudden trouble seeing
- sudden trouble walking, dizziness, loss of balance or coordination
- lightheadedness or fainting
- dialysis access stops working
- not feeling a vibration (“thrill”) over the dialysis access area

JESDUVROQ may cause other serious side effects, including:

- Risk of hospitalization for heart failure
- High blood pressure
- Damage to the lining of the stomach, the tube that connects the mouth and stomach (esophagus), and intestines (gastrointestinal [GI] erosion)
- Cancer

These are not all the possible side effects of JESDUVROQ. Call your doctor for medical advice about side effects.

IMPORTANT SAFETY INFORMATION (cont.)

JESDUVROQ may cause other serious side effects, including: (cont.)

- **Damage to the lining of the stomach, the tube that connects the mouth and stomach (esophagus), and intestines (gastrointestinal [GI] erosion).** Your risk of gastrointestinal erosion may increase if you have a history of GI erosion, stomach ulcers (peptic ulcer disease), use certain medicines that increase the risk of GI 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; nausea or vomiting; blood in your vomit or stool; black, tarry stools; trouble swallowing; 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.
- blood clots (thrombotic vascular events) including heart attack, stroke, and blood clots in the dialysis access, legs, or lungs.
- stomach area (abdominal) pain.

These are not all the possible side effects of JESDUVROQ. Call your doctor for medical advice about side effects.

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

Please see additional Important Safety Information throughout and accompanying Important Facts, including Serious Side Effects for JESDUVROQ.

JESDUVROQ is the first in a novel class of treatment in Anemia of CKD for adults on dialysis for at least 4 months.



Talk to your healthcare team to learn if JESDUVROQ may be right for you.



Visit [JESDUVROQ.com](https://www.jesduvroq.com) to learn more.

APPROVED USE

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.

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).
- in people who are not on dialysis.

IMPORTANT SAFETY INFORMATION

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).

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Please see additional Important Safety Information throughout and accompanying Important Facts, including Serious Side Effects for JESDUVROQ.

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Important Facts about JESDUVROQ

Read these Important Facts carefully before taking JESDUVROQ. These Important Facts do not take the place of talking to your healthcare provider (HCP) about your medical condition or treatment. For additional product information, see full Prescribing Information, including BOXED WARNING and Medication Guide, at www.JESDUVROQ.com or call 1-888-825-5249.

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; trouble breathing or shortness of breath; pain in your leg or arm, with or without swelling; unusual coolness or warmth in arm or leg; sudden confusion, trouble speaking, or trouble understanding others' speech; sudden numbness or weakness in your face, arm, or leg, especially on one side of your body; sudden trouble seeing; sudden trouble walking, dizziness, loss of balance or coordination; lightheadedness or fainting; dialysis access stops working; and do not feel a vibration ("thrill") over the dialysis access area.

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; or 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.
- If you take more than your prescribed dose of JESDUVROQ, contact your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of JESDUVROQ?

JESDUVROQ may cause other serious side effects, including:

- **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; swelling of your feet, ankles, or legs; sudden weight gain; and 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 (GI) erosion may increase if you have a history of GI erosion, stomach ulcers (peptic ulcer disease), use certain medicines that increase the risk of GI 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; nausea or vomiting; blood in your vomit or stool; black, tarry stools; trouble swallowing; and 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?"
- 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 to get more information

The risk information provided here is not complete. To learn more, talk to your healthcare provider (HCP). Visit www.JESDUVROQ.com or call 1-888-825-5249 to get FDA-approved product labeling, including BOXED WARNING and Medication Guide.

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