

Daprotab™

Daprodustat INN

Presentation

Daprotab™ 1: Each film coated tablet contains Daprodustat INN 1 mg.
Daprotab™ 2: Each film coated tablet contains Daprodustat INN 2 mg.
Daprotab™ 4: Each film coated tablet contains Daprodustat INN 4 mg.
Daprotab™ 6: Each film coated tablet contains Daprodustat INN 6 mg.

Description

Daprotab contains Daprodustat, an inhibitor of hypoxia inducible factor (HIF), prolyl 4- hydroxylases (PH)1, PH2 and PH3.

Mechanism of action

Daprodustat is a reversible inhibitor of HIF-PH1, PH2 and PH3. 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.

Indications

Daprodustat 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.

Dosage and administration

Correct and exclude other causes of anemia (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding) and Iron stores, Liver condition before initiating Daprodustat.

Adults with anemia due to CKD receiving dialysis for at least 4 months

For adults not being treated with an ESA, the starting dose of Daprodustat is based on the hemoglobin level.

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

For adults being switched from an ESA to Daprodustat, the starting dose of Daprodustat is based on the dose regimen of the ESA at the time of substitution.

Current Dose of ESA			Dose of Daprodustat
Epoetin Alfa Intravenous (IU/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	20 to 30	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

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.

Missed dose

If a dose of Daprodustat 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.

Method of administration

Daprodustat can be taken with or without food and without regard to concomitant administration of iron or phosphate binders. Daprodustat should be swallowed whole.

Adverse reaction

Most common adverse reactions (≥10%) are hypertension, thrombotic vascular events, and abdominal pain.

Contraindications

Strong cytochrome P450 2C8 (CYP2C8) inhibitors such as gemfibrozil & uncontrolled hypertension.

Warnings and precautions

Daprodustat tablets should be used in caution. It may increase the risk of hospitalization for Heart Failure patients, may worsen hypertension in patients may cause gastrointestinal erosion. It is not indicated for treatment of anemia of CKD in patients who are not dialysis-dependent and may have unfavorable effects on cancer growth. It is not recommended in case of active malignancy.

Drug interactions

Reduce starting dose in case of moderate CYP2C8 Inhibitors.

Use in specific populations

Pregnancy: May cause fetal harm; **Lactation:** Breastfeeding not recommended until one week after the final dose; **Hepatic impairment:** Reduce the starting dose in patients with moderate hepatic impairment (Child-Pugh Class B). Daprodustat not recommended in severe hepatic impairment (Child-Pugh Class C); **Overdosage:** Headache and gastrointestinal adverse reactions (e.g., nausea) may be seen with acute overdose with Daprodustat.


Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial pack

Daprotab™ 1 : Each box contains 3 blister strips of 10 tablets.
Daprotab™ 2 : Each box contains 2 blister strips of 10 tablets.
Daprotab™ 4 : Each box contains 2 blister strips of 10 tablets.
Daprotab™ 6 : Each box contains 1 blister strip of 10 tablets.

Manufactured by

 **Incepta Pharmaceuticals Ltd**

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